

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 1

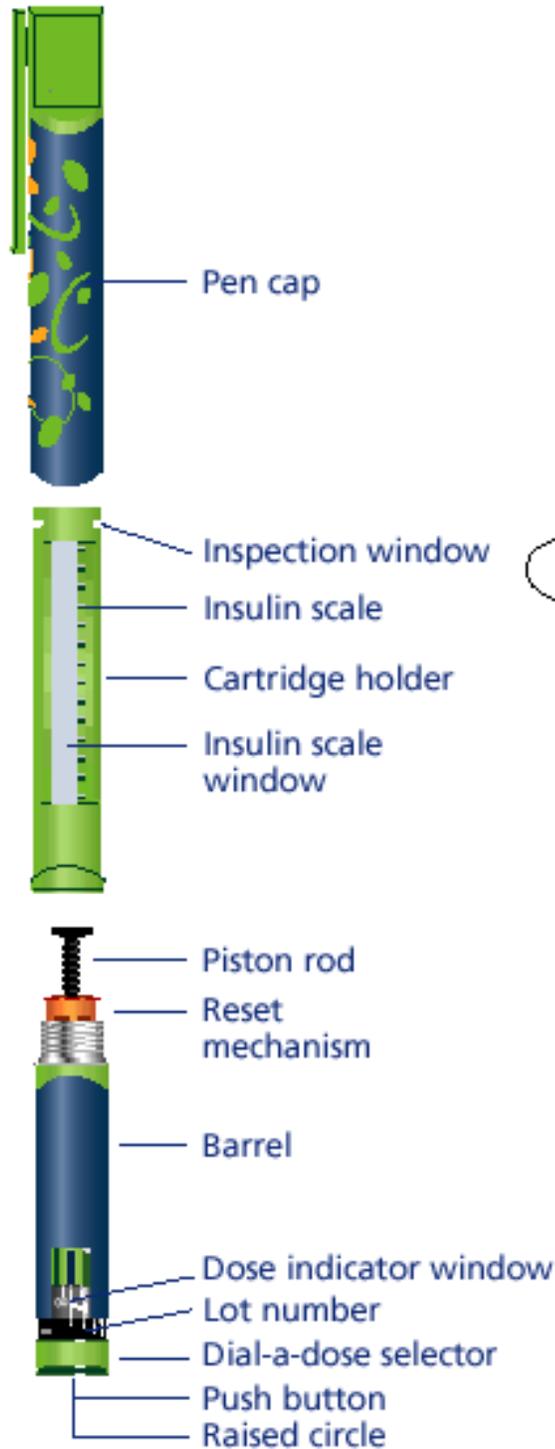


NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 2

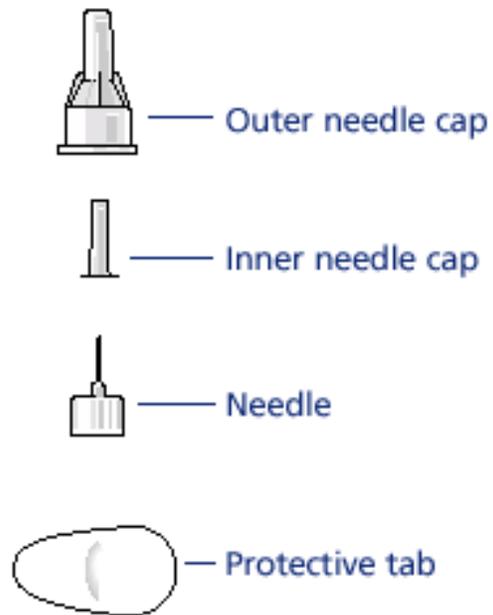


NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 3

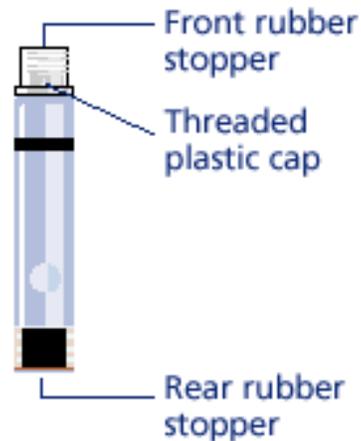
NovoPen® Junior Insulin Delivery Device



NovoFine® Disposable Needle



PenFill® Cartridge (3 mL)



Need Help?
Call 1-800-727-6500

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 4

4

5 **NovoPen[®] Junior Instruction** 6 **Manual**

7

8 **Dial-A-Dose Insulin Delivery System**

9

10 **INTRODUCTION**

11

12

13

14

15 NovoPen[®] Junior delivers a minimum dose of 1 unit to a maximum dose of 35
16 units of insulin in half unit steps. A raised circle on the push button makes it easy
17 for you to know your NovoPen Junior from the ordinary NovoPen 3. This booklet
18 includes everything you need to know about using the NovoPen Junior. Please
19 read it carefully before using your NovoPen Junior for the first time.

20

21 The NovoPen Junior is designed for use with:

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

The NovoPen Junior is designed for use with:

- PenFill[®] 3 mL cartridges.
- NovoFine[®] disposable needles.

NovoFine disposable needles are for single-use only.
You will also need alcohol swabs.

If you have any questions about your NovoPen Junior insulin delivery system,
please call Novo Nordisk Pharmaceuticals, Inc. at 1-800-727-6500.

Please complete and return the NovoPen Junior warranty card.

See **Important Things to Know** and **Important Notes** on pages 33-35.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 5

38 **HOW TO USE THIS BOOKLET**

39

40 **This booklet gives you step-by-step instructions for using the NovoPen**
41 **Junior.**

42

43 Begin by reviewing the drawing layout of the parts of the NovoPen Junior, PenFill
44 3 mL cartridge, and NovoFine disposable needle. The inside front cover opens
45 out so you have a handy reference while you read the rest of the booklet.

46

47 Most pages contain a drawing on the right with numbered instructions to the left
48 of the drawing.

49 **Important additional information is given below the drawing.**

50

51 We suggest that you **read the text and look at the drawing** to make sure that
52 you understand each step thoroughly.

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

75

76

77

78

79

80

81

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 6

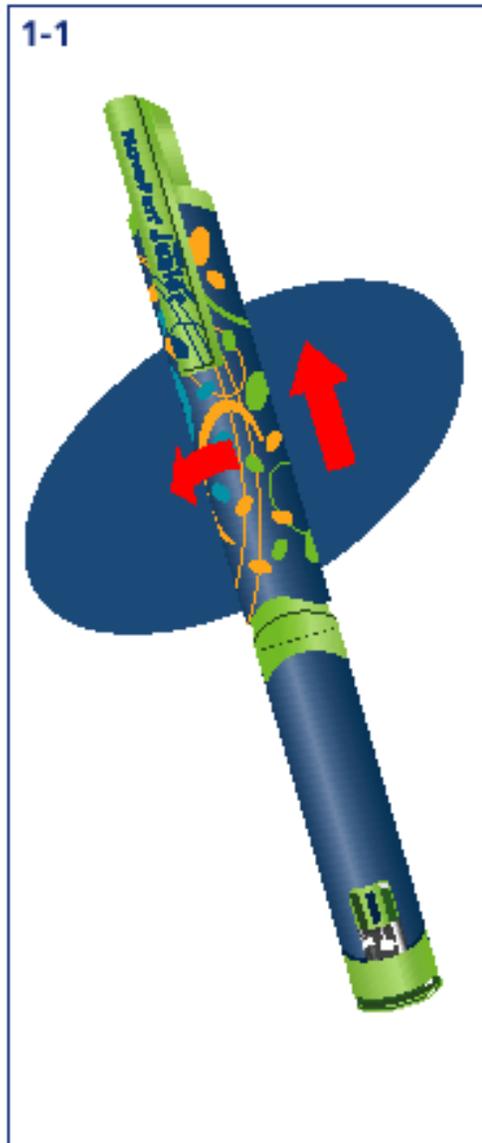
82	TABLE OF CONTENTS	
83		
84	SECTION 1:	
85	Preparing the NovoPen Junior.....	5
86		
87	SECTION 2:	
88	Inserting the PenFill 3 mL Cartridge.....	8
89		
90	SECTION 3:	
91	Attaching the NovoFine Disposable Needle.....	12
92		
93	SECTION 4:	
94	Doing an Air Shot	16
95		
96	SECTION 5:	
97	Giving the Injection	20
98		
99	SECTION 6:	
100	Removing the NovoFine Disposable Needle.....	24
101		
102	SECTION 7:	
103	Removing the PenFill 3 mL Cartridge.....	26
104		
105	FUNCTION CHECK	28
106		
107	STORAGE.....	31
108		
109	MAINTENANCE.....	32
110		
111	IMPORTANT THINGS TO KNOW.....	33
112		
113	IMPORTANT NOTES.....	34
114		
115	WHAT TO DO IF.....	36
116		
117	WARRANTY	37
118		

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 7

119 **SECTION 1** **Preparing the NovoPen Junior**
120

121 **Remove the device cap:**

- 122 1. Remove the NovoPen Junior from the case.
123 2. Gently twist the pen cap until the cap separates from the barrel.
124 3. Pull the pen cap straight up to remove it.
125



Need Help?
Call 1-800-727-6500

126
127
128
129
130
131
132

If you use more than one insulin product (such as Novolin® R, Novolin® N, Novolin® 70/30, or NovoLog®), use a separate insulin delivery device for each product.

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 8

133 **SECTION 1 (cont.)**

134

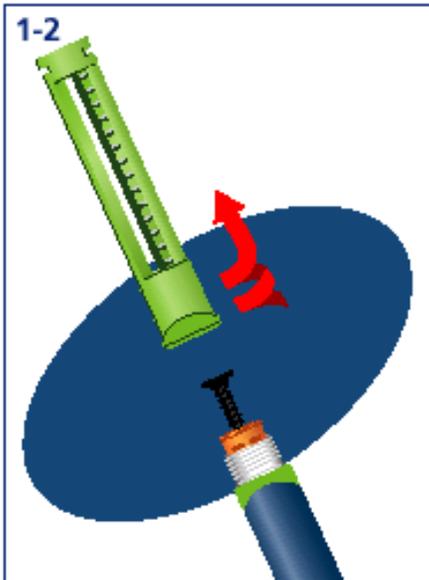
135 **Separate the cartridge holder from the barrel:**

136

137

138

4. Unscrew and remove the cartridge holder from the barrel.



139

140

141

142

143

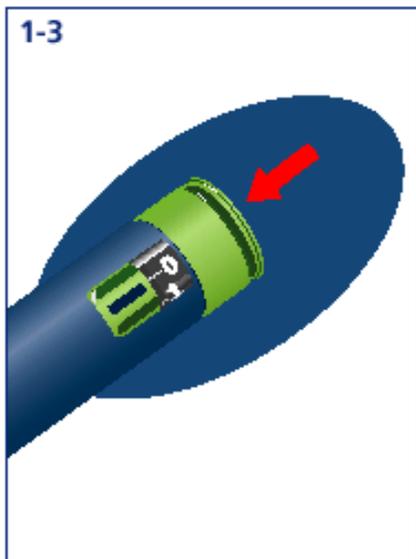
144

145

146

Make sure the dose indicator window shows zero:

5. Press the push button all the way in until zero (0) appears in the window. The zero should be lined up with the stripe below the dose indicator window.



147

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 9

148 6

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 10

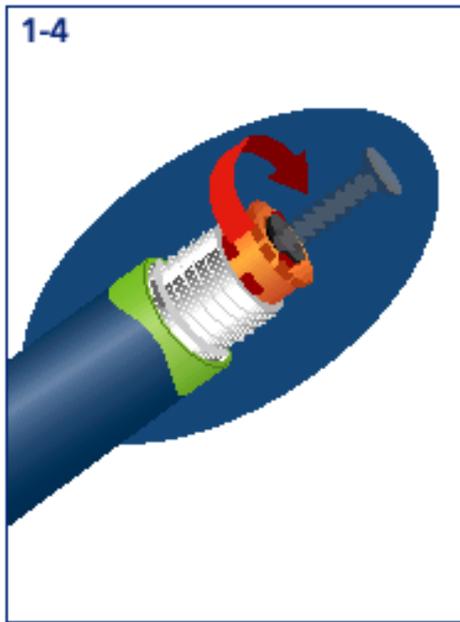
149
150
151
152
153
154
155
156
157
158
159

SECTION 1 (cont.)

The end of the piston rod should be flat against the end of the reset mechanism prior to inserting each new PenFill 3 mL cartridge. It should not be sticking out.

If the piston rod is sticking out:

Turn the end of the reset mechanism in a clockwise direction until it is no longer sticking out. Never push the piston rod back in.



160

Need Help?
Call 1-800-727-6500

161
162
163
164
165
166
167
168
169
170

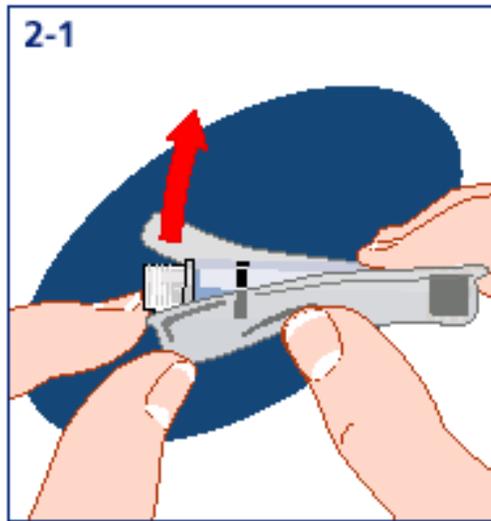
You should never reset the piston rod until it is time to remove the used PenFill 3 mL cartridge and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-800-727-6500) so that we may go over your technique with you.

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 11

171 **SECTION 2** **Inserting the PenFill 3 mL Cartridge**
172

- 173 1. To remove the PenFill cartridge from its wrapper, push the cartridge
174 through the foil side of the packaging. Always make sure that the PenFill
175 cartridge you use contains the correct type of insulin (such as Novolin R,
176 Novolin N, Novolin 70/30, or NovoLog). If you are treated with more than
177 one type of insulin in PenFill cartridges, you should use a separate insulin
178 delivery device for each type of insulin. Before use, check that the PenFill
179 cartridge is full and intact. If not, do not use it.
180



- 181
182
183 2. In the PenFill Information For The Patient leaflet, you will find instructions
184 on how to prepare the insulin if the PenFill contains a suspension insulin
185 (white and cloudy insulin) such as Novolin N or Novolin 70/30.
186
187

188 Each PenFill 3 mL cartridge contains a total of 300 units of insulin. Make sure
189 you are using the correct type of insulin. On the glass part of the cartridge is the
190 name of the insulin.

191
192 Each PenFill cartridge is for single-person use only. **DO NOT** share the same
193 cartridge with anyone even if you attach a new disposable needle for each
194 injection. Sharing the cartridge can spread disease.
195 Use only a new PenFill 3 mL cartridge when loading the NovoPen Junior. Never
196 load a partially filled cartridge.
197 Never try to refill a used PenFill 3 mL cartridge.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 12

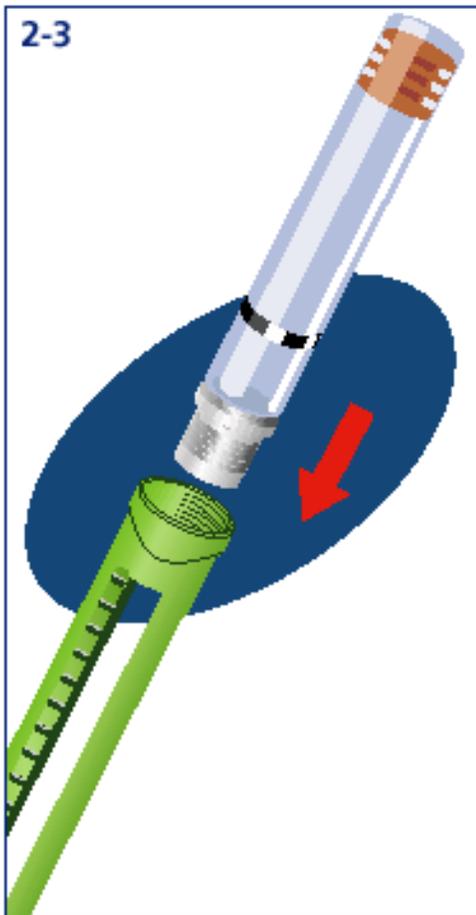
200
201
202
203
204
205
206
207

9

SECTION 2 (cont.)

Insert the PenFill cartridge:

2. Hold the cartridge holder so the wider opening is up.
3. Drop the PenFill cartridge into the cartridge holder, plastic cap first.



208
209
210
211
212
213
214

A threaded plastic cap surrounds the end of the PenFill® cartridge, like the cap on a bottle. In the center is the front rubber stopper.

The rear rubber stopper is at the other end of the PenFill cartridge.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 13

215 **SECTION 2 (cont.)**

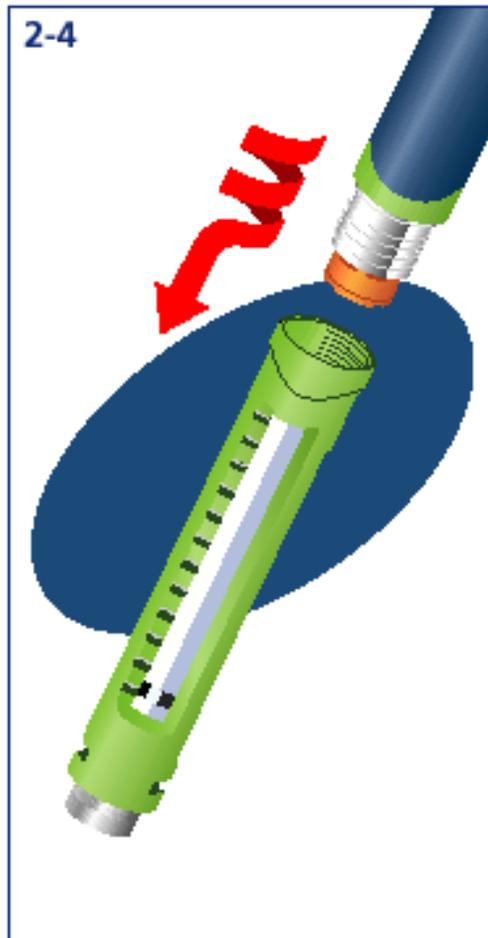
216

217 **Re-attach the cartridge holder:**

218

219 4. Screw the barrel into the cartridge holder completely until it is tight.

220



221

222

223

224

225 You can see the cartridge in the insulin scale window. The cartridge holder has a
226 scale with marks showing about how much insulin is left in the PenFill cartridge.

227

228

229

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 14

230 **SECTION 3 Attaching the NovoFine® Disposable Needle**

231

232 At the end of the cartridge holder are two inspection windows. You can see the
233 cartridge through these windows.

234

235 **If you use a suspension insulin (white and cloudy) such as Novolin® N or**
236 **Novolin® 70/30, use the windows to check if there is enough insulin left for**
237 **proper mixing.** (see below)

238

239 **Check the amount of insulin remaining:**

240

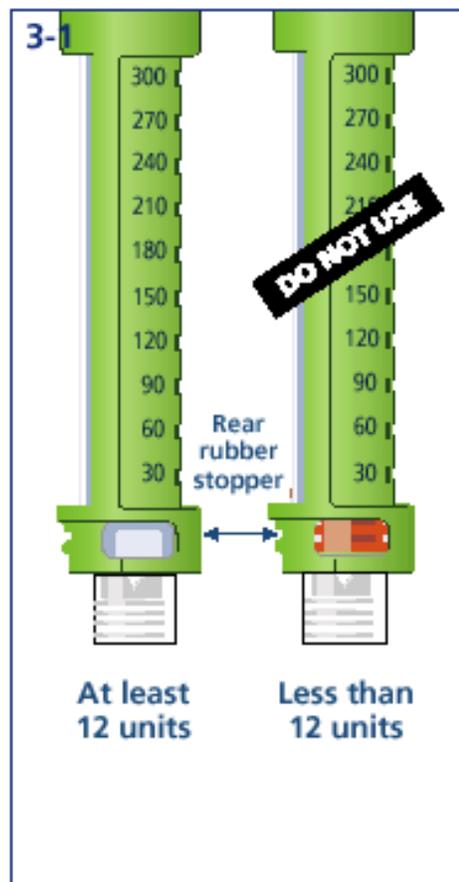
- 241 ▪ If the rear rubber stopper cannot be seen in the inspection window, you
- 242 have enough insulin for mixing left in the cartridge.
- 243 ▪ If the rear rubber stopper can be seen in the inspection window, you do
- 244 not have enough insulin left in the cartridge and must insert a new PenFill
- 245 3 mL cartridge.

246

247 See Section 7 for instructions on removing a PenFill cartridge and Section 2 for
248 inserting a new one.

249

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 15



250
251 12

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 16

252 **SECTION 3 (cont.)**

253

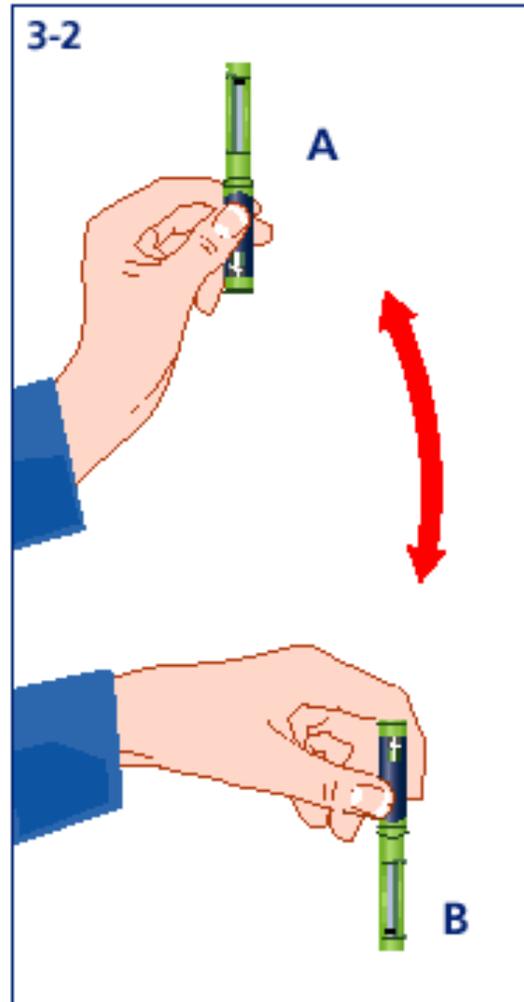
254 **For users of suspension insulin (white and cloudy) such as Novolin N or**
255 **Novolin 70/30:**

256

257 **Always remix the insulin before each injection.**

258 To remix the insulin, turn the NovoPen Junior up and down between positions **A**
259 and **B** 10 times or until the insulin looks uniformly white and cloudy

260



Need Help?
Call 1-800-727-6500

261

262

263

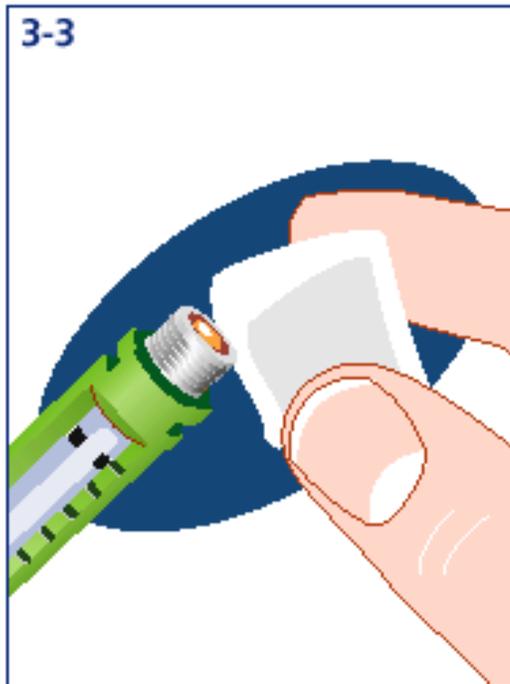
264

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 17

265
266
267
268

SECTION 3 (cont.)

1. Wipe the front rubber stopper with an alcohol swab.



269
270
271
272
273
274

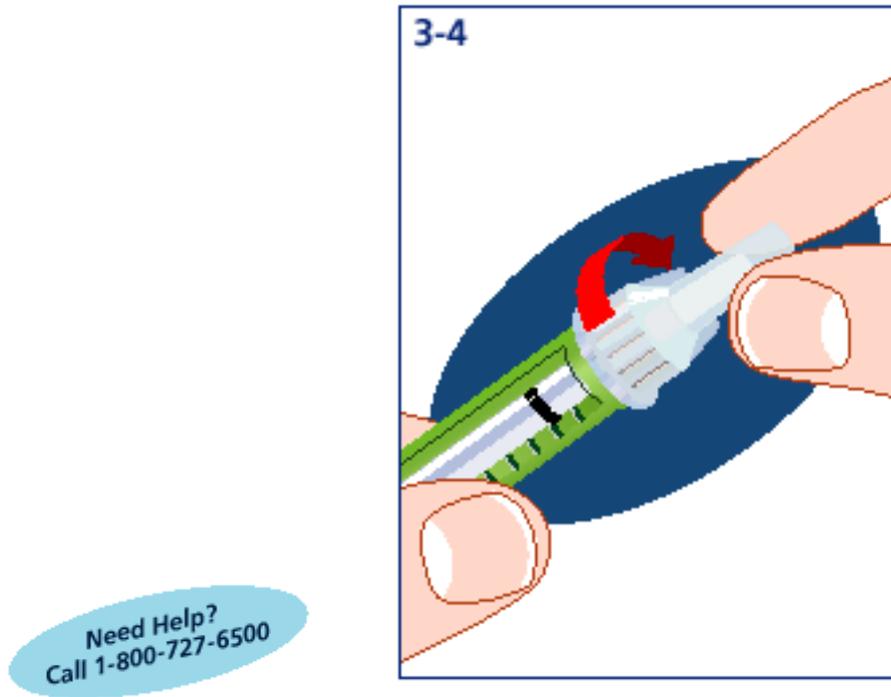
You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same PenFill cartridge.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 18

275 **SECTION 3 (cont.)**

276
277
278
279
280

2. Remove the protective tab from the NovoFine disposable needle.
3. Screw the NovoFine disposable needle firmly onto the PenFill 3 mL cartridge until it is tight.



281
282
283
284
285
286
287
288

Never place a NovoFine disposable needle on your NovoPen Junior until you are ready to do an air shot and give an injection. If the NovoFine needle is left on, some liquid may leak out of the PenFill cartridge. This may cause a change in the strength of the suspension insulin such as Novolin N or Novolin 70/30.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 19

289

290

SECTION 4 Doing an Air Shot

291

292

The PenFill cartridge may contain an air bubble, and small amounts of air may collect in the needle and PenFill cartridge when you use them. To avoid injecting air and to ensure proper dosing, you must perform an air shot before each injection.

293

294

295

296

297

Before doing the air shot, the dose indicator window must show zero (0).

298

299

If you use a suspension insulin, such as Novolin N or Novolin 70/30 and have used the PenFill cartridge for previous injections, make sure there is enough insulin left in the PenFill cartridge to properly mix the insulin (see page 12). If there is enough insulin left in the PenFill cartridge, see the next page for instructions.

300

301

302

303

304

305

16

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 20

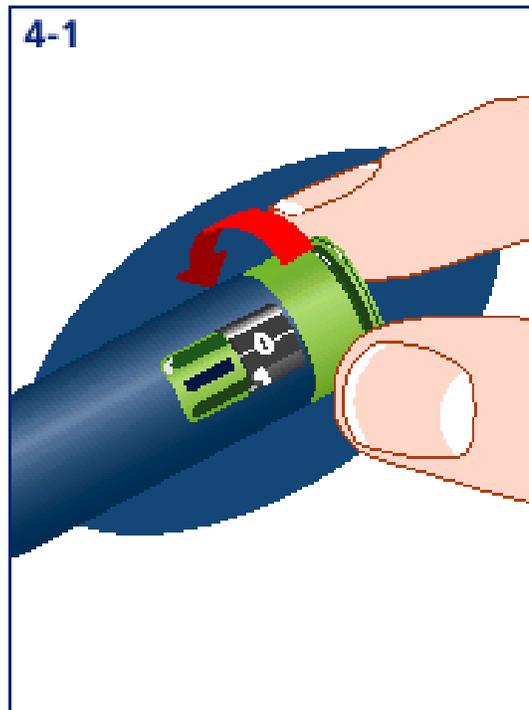
306 **SECTION 4 (cont.)**

307

308 **Set the NovoPen Junior for the air shot:**

309

- 310 1. Turn the dial-a-dose selector to 2 units. Full units are shown as numbers.
311 Half units are shown as long lines between the numbers.
312



Need Help?
Call 1-800-727-6500

313

314

315 **If you dial more than 2 units, DO NOT turn the dial back to zero (0).** If you
316 do, the extra insulin will squirt out of the needle. You may complete the air shot
317 with the number of units you have dialed or refer to Section 5 on page 21 for
318 instructions on how to reset the dose to zero.

319

320

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 21

321 **SECTION 4 (cont.)**

322

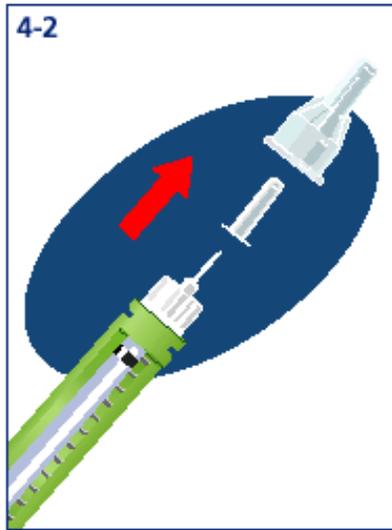
323 **Uncap the NovoFine needle:**

324

- 325 2. Pull off the outer needle cap and set aside.
326 3. Pull off the inner needle cap and discard.

327

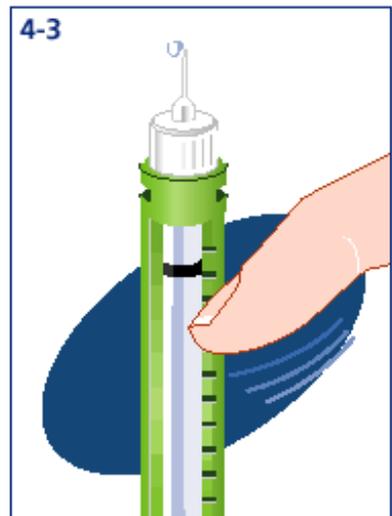
328 Do not use the needle if it is bent or damaged.
329



330

331

- 332 4. Hold the NovoPen Junior with the NovoFine needle pointing up.
333 5. Tap the cartridge holder with your finger a few times to raise any air
334 bubbles that may be present to the top of the cartridge.
335



336

337

338

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 22

339 **SECTION 4 (cont.)**

340

341 **Do the air shot:**

342

343 6. Press the push button all the way in. A drop of insulin should appear at the
344 needle tip.

345

346 **If no insulin appears, repeat the following steps, until a drop of insulin**
347 **appears:**

348

349 a. Make sure the NovoFine needle is securely attached.

350 b. Dial 2 units.

351 c. Tap the cartridge holder with your finger.

352 d. Press the push button all the way in.

353

354 There may still be some small air bubble(s) in the PenFill cartridge after this, but
355 they will not affect your dose and they will not be injected.

356

Need Help?
Call 1-800-727-6500



357

358

359 When you press the push button, the piston rod presses against the rear rubber
360 stopper. This moves the rear rubber stopper and pushes the correct amount of
361 insulin up through the needle.

362

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 23

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 24

364 **SECTION 5 Giving the Injection**

365

366 **Be sure to do an air shot before giving each injection (see pages 16-19).**

367

Select the dose:

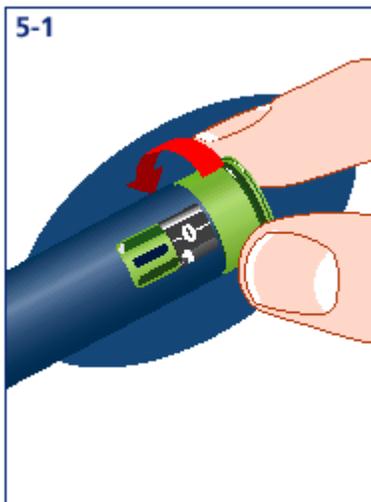
368

369 1 Check that the dial-a-dose selector is set to zero. If not, follow the
370 instructions on the next page. Turn the dial-a-dose selector until you see
371 the correct number of units in the dose indicator window. Full units are
372 shown as numbers. Half units are shown as long lines between the
373 numbers.

374

375 **DO NOT use the clicking sound as a guide for selecting your dose.**

376



377

378

379 The NovoPen Junior can deliver insulin in half unit steps from a minimum dose
380 of 1 unit to a maximum dose of 35 units.

381

382 **If you dial more than your dose, DO NOT turn the dial back to zero (0).** If you
383 do, the extra insulin will squirt out of the needle. For instructions on how to reset
384 the dose to zero (0) so you can start again, see the next page.

385

386

387 20

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 25

388 **SECTION 5 (cont.)**

389

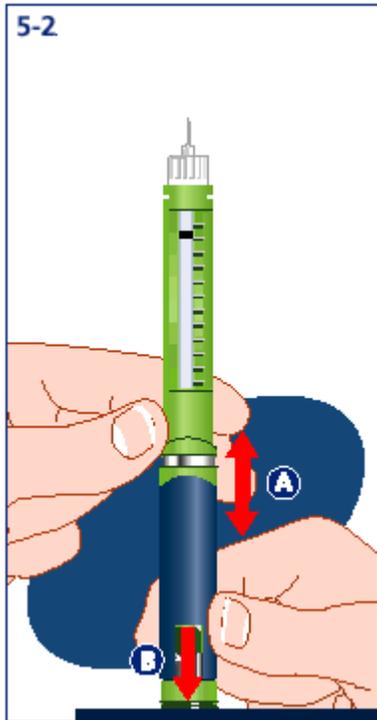
390 If you dial a larger dose than you need, pull the barrel and the cartridge holder
391 apart, as shown in the drawing **A**. While holding them apart, gently press the
392 push button against a hard surface and release your grip **B**. Your dose indicator
393 window should be back to zero (0).

394

395 You can now dial the correct number of units.

396

Need Help?
Call 1-800-727-6500



397

398

399

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 26

400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420

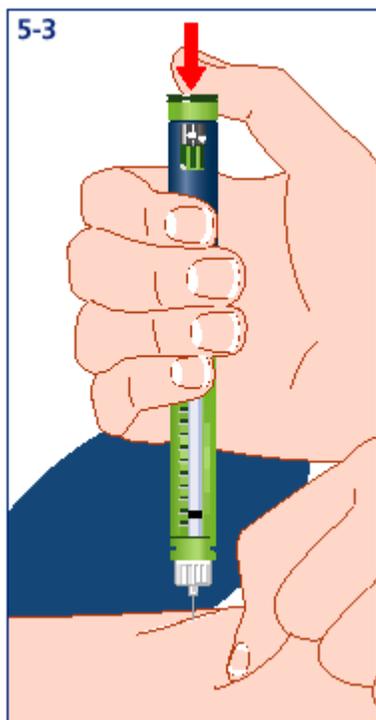
SECTION 5 (cont.)

Giving the injection:

2. After the air shot is done and you have chosen the correct number of units, insert the NovoFine needle in the correct injection site on your body. (Use the injection technique recommended by your health care professional). If you use a suspension insulin such as Novolin N or Novolin 70/30, mix the insulin (see page 13, Section 3) and make sure the insulin looks uniformly white and cloudy before you inject.
3. Press the push button **as far as it will go** to deliver the insulin. Do not force it.

To ensure that all the insulin is injected, keep the NovoFine needle in the skin for several seconds after injection with your thumb on the push button. Keep the push button fully depressed until after the NovoFine needle has been withdrawn.

Important: Never turn the dial-a-dose selector to inject the insulin.



421
422
423
424
425

When you get near the end of a PenFill cartridge, you may need to give yourself two injections to receive your full dose. Check the dose indicator window after giving an injection. If zero does not appear in the dose indicator window, you did

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 27

426 not receive your full dose. See the next page for instructions on how to get the
427 remaining part of your dose.
428
429 22

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 28

430

431 **SECTION 5 (cont.)**

432

433 **4. Check the dose indicator window to make sure it shows zero (0). If**
434 **zero does not appear, you did not receive the full dose.**

435

436 If the dose indicator window does not show zero, there were not enough units of
437 insulin in the PenFill cartridge for you to receive the full dose. The dose indicator
438 window shows the number of units that you did not receive.

439

440 For example, if you dial **25** units and there are only **20** units left in the PenFill
441 cartridge, after the injection the number in the dose indicator window will be
442 **5** ($25-20 = 5$). If this happens, proceed with the following steps to get the
443 remaining part of your dose:

444

- 445 a. Note the number of units in the dose indicator window.
- 446 b. Remove the NovoFine needle (see Section 6).
- 447 c. Remove the empty PenFill 3 mL cartridge (see Section 7).
- 448 d. Insert a new PenFill 3 mL cartridge (see Section 2).
- 449 e. Attach a NovoFine needle (see Section 3).
- 450 f. Do an air shot (see Section 4).
- 451 g. Dial the number of units noted in step a.
- 452 h. Give the injection.

453

454



455

456

457

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 29

458 **SECTION 6 Removing the NovoFine Disposable Needle**

459

460 **Remove the NovoFine disposable needle:**

461

462 1. After the injection, remove the needle without replacing the cap.

463

464 2. Hold the cartridge holder firmly while you unscrew the NovoFine
465 disposable needle.

466

467 3. Place the NovoFine disposable needle in a puncture-resistant disposable
468 container.

469

470 Health care professionals, relatives and other caregivers should also follow the
471 above instructions to eliminate the risk of unintended needle penetration.

472

473

474

475

476 **The NovoFine disposable needle must be removed immediately after each**
477 **injection without replacing the cap.** If the NovoFine disposable needle is not
478 removed, some liquid may leak out of the PenFill cartridge. This may cause a
479 change in the strength of suspension insulins (white and cloudy) such as Novolin
480 N or Novolin 70/30.

481

482 For information on how to throw away needle containers properly, contact your
483 local trash company.

484

485 24

486

487

488 **SECTION 6 (cont.)**

489

490 **Replace the pen cap:**

491

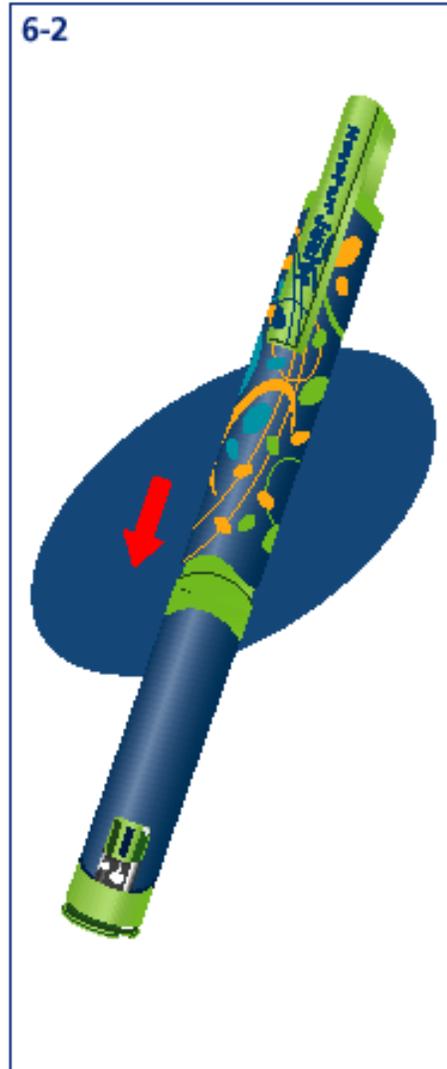
492 4. After you remove the disposable needle, hold the pen cap so that the clip
493 is lined up with the dose indicator window.

494

495 5. **Gently slide** the pen cap onto the barrel.

496

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 30



Need Help?
Call 1-800-727-6500

497
498
499
500

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 31

501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520

SECTION 7 Removing the PenFill 3 mL Cartridge

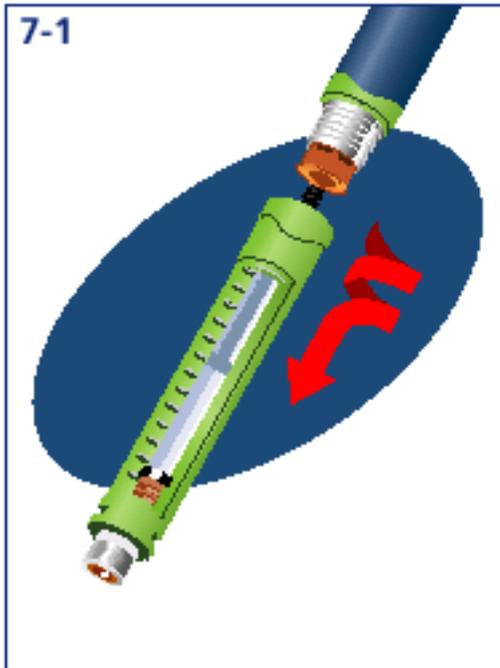
You will need to remove the PenFill cartridge for the following reasons:

- ~~When t~~he PenFill cartridge is empty.
- **If you use a suspension insulin such as Novolin N or Novolin 70/30:**

When you see the rear rubber stopper in the inspection window, then you do not have enough insulin left in the PenFill cartridge for proper mixing.

Remove the barrel:

1. Remove the pen cap.
2. Hold the NovoPen Junior with the dose indicator window at the top.
3. Unscrew the barrel from the cartridge holder.



521
522
523

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 32

524 **SECTION 7 (cont.)**

525

526 **Remove the PenFill 3 mL cartridge:**

527

528

4. Tip the cartridge holder. The PenFill cartridge will drop out.

529

530

5. Press the push button all the way in until zero (0) appears in the window.

531

532

6. Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out (refer to figure 1-4 on page 7).

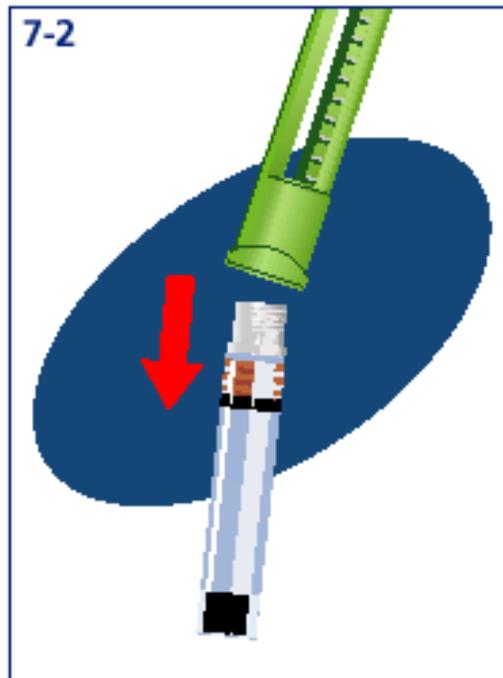
533

534

7. To insert a new PenFill cartridge, please refer to Section 2.

535

536



Need Help?
Call 1-800-727-6500

537

538

539

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-800-727-6500) so that we may go over your technique with you.

540

541

542

543

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 33

544 **FUNCTION CHECK**

545

546 You should regularly check the functioning of your NovoPen Junior, (for example,
547 once a month or before starting a new box of PenFill cartridges). The function
548 check is done by delivering 20 units of insulin into the outer needle cap. You will
549 not be injecting insulin into your body.

550

551 Always check the functioning of the NovoPen Junior if you suspect it has been
552 damaged or if you are uncertain that it is delivering the correct dose.

553

554 Do not use NovoPen Junior unless you are sure that it is working properly.

555

556 **To perform the function check:**

557

558 1. Attach a NovoFine disposable needle (see pages 12-15).

559

560 2. Do an air shot (see pages 16-19).

561

562 28

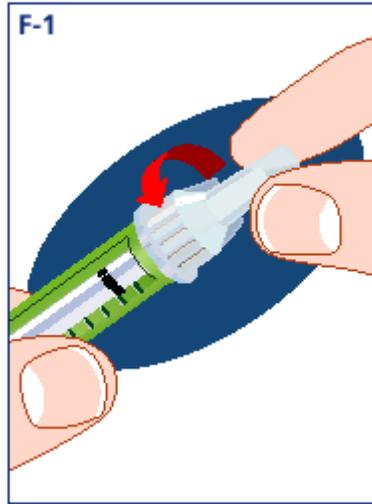
563

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 34

564
565
566
567
568
569
570

FUNCTION CHECK (cont.)

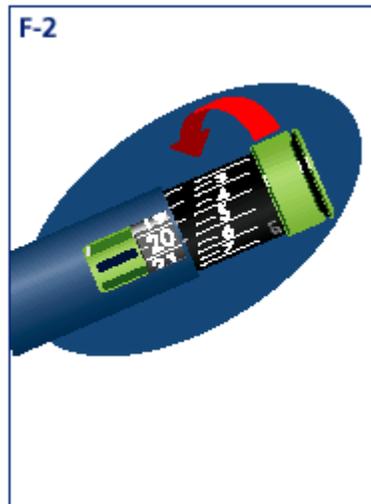
3. **Do not replace the inner needle cap.** Place the outer needle cap securely over the exposed NovoFine needle.



571
572
573
574
575
576

Expel 20 units of insulin into the outer needle cap:

4. Turn the dial-a-dose selector so the dose indicator window shows 20.



Need Help?
Call 1-800-727-6500

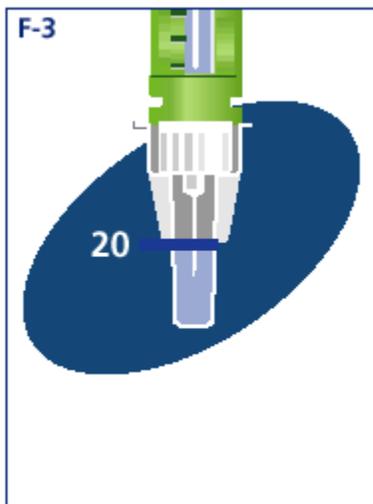
577
578
579

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 35

580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596

FUNCTION CHECK (cont.)

5. Hold the NovoPen Junior so the NovoFine disposable needle is pointing down.
6. Slowly press the push button **as far as it will go**.
7. Check the dose indicator window to see if it shows zero (0). If it does not show zero (0), there is not enough insulin in the cartridge to do a function check. Insert a new PenFill cartridge (see pages 8-11) and repeat the function check. If there is enough insulin in the cartridge but the dose indicator window does not show zero, repeat the FUNCTION CHECK. If you do not see zero after repeating the above steps, do not use your NovoPen Junior. Contact Novo Nordisk Pharmaceuticals, Inc. at our toll free number (1-800-727-6500).



597
598
599
600
601
602
603
604
605
606
607
608
609
610
611

The insulin should fill the bottom part of the outer needle cap. This indicates the device is functioning properly.

If the insulin **does not fill or overfills** this part of the cap, review the function check procedure. Then repeat the function check with a new NovoFine disposable needle and outer needle cap.

If the second function check also shows under- or over-filling, do not use your NovoPen Junior.

DO NOT try to repair a NovoPen Junior that you think is not working properly.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 36

612 See Warranty section for further information.
613
614 30

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 37

615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647

STORAGE

Guidelines for storing the NovoPen Junior and PenFill 3 mL cartridges:

- PenFill cartridges should be stored in a cool place, such as in a refrigerator, but not in ~~the~~ freezer.
- After the first use of PenFill cartridge in the NovoPen Junior, the NovoPen Junior (with the PenFill cartridge inside) can be kept at room temperature below 86°F (30°C) for the amount of time days specified listed in the PenFill Information for the Patient leaflet for the type of insulin you are using.
- **Do not store** the NovoPen 3 Junior (with the PenFill cartridge inside) in a refrigerator or areas where there may be extreme temperatures or moisture, such as in your car.
- **The expiration date printed on the cartridge is for unused cartridges under refrigeration. Never use the cartridge after the expiration date on the cartridge or its box.**
- Store the NovoPen Junior **without** the NovoFine needle attached and **with** the pen cap in position.
- For information on storing PenFill cartridges, see the package leaflet that comes in the PenFill cartridge box.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 38

648 **MAINTENANCE**

649

650 **Guidelines for maintaining the NovoPen Junior.**

651

652 **Be sure to:**

653

654 1. Clean it by wiping with a soft cloth moistened with alcohol.

655

656 2. Protect it from dust, dirt, and moisture when not in its case.

657

658

659 **Make certain you:**

660

661 1. **Do not** soak it in alcohol, do not wash it in soap and water, or do not
662 lubricate it, since this may cause damage.

663

664 2. **Do not** expose it to excessive pressure or blows.

665

666 3. **Do not** drop it.

667

668 32

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 39

669 **IMPORTANT THINGS TO KNOW**

670

671

- The NovoPen Junior is not recommended for the blind or visually impaired, without the assistance of a sighted individual trained to use it.

672

673

674

- If you use more than one type of insulin (such as Novolin R, Novolin N, Novolin 70/30, or NovoLog), use a separate insulin delivery device for each type of insulin.

675

676

677

678

- Use only a new PenFill 3 mL cartridge when loading the NovoPen Junior. Never load the NovoPen Junior with a partially filled PenFill cartridge.

679

680

681

- Always keep a spare insulin delivery system available, in case your NovoPen Junior is lost or damaged.

682

683

684

- Keep the NovoPen Junior, PenFill cartridges, and NovoFine needles out of the reach of children. The American Diabetes Association recommends that insulin should be self-administered. The proper age for initiating this should be assessed by the adult caregiver.

685

686

687

688

689

- Keep the NovoPen Junior away from areas where temperatures may get too hot or too cold such as a car or refrigerator.

690

691

692

- The NovoPen Junior is designed for use with PenFill 3 mL insulin cartridges and NovoFine single-use disposable needles.

693

694

695

696

697

698

699

Novo Nordisk is not responsible for any consequences arising from the use of the NovoPen Junior with products other than PenFill 3 mL insulin cartridges and NovoFine single-use disposable needles.

NDA 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 40

700 **IMPORTANT NOTES**

701

702 **The following is a review of some important information about the use and**
703 **care of your NovoPen Junior.**

704

705

706 **Before each injection, be certain:**

707

708 1. The NovoPen Junior contains the correct insulin cartridge (such as
709 Novolin R, Novolin N, Novolin 70/30, or NovoLog), if you use more than
710 one type of insulin.

711

712 2. The PenFill cartridge contains enough insulin for mixing, if you use a
713 suspension insulin (white and cloudy) such as Novolin N or Novolin 70/30.

714

715 3. To do an air shot with the NovoFine needle pointing up before each
716 injection.

717

718

719 **Be sure to:**

720

721 1. Check the dose indicator window after each injection to make sure you
722 have received your full dose (see page 23, Section 5).

723

724 2. Remove the NovoFine needle immediately after each injection without
725 replacing the cap.

726

727 3. Select your dose only by using the number in the dose indicator window.

728

729 4. Perform the function check regularly or if you think your NovoPen Junior is
730 not working properly.

731

732 34

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 41

733 **IMPORTANT NOTES (cont.)**

734

735 **Make certain you:**

736

- 737 1. **DO NOT** place a NovoFine needle on the NovoPen Junior until you are
738 ready to do an air shot and give an injection or do a function check.
739 Remove the needle immediately after each injection without replacing the
740 cap. If the NovoFine needle is not removed, some liquid may leak out of
741 the PenFill cartridge. This may cause a change in the strength of
742 suspension insulin (white and cloudy) such as Novolin N or Novolin 70/30.
743
744 2. **DO NOT** use the clicking sound to set your insulin dose.
745
746 3. **DO NOT** try to refill a PenFill cartridge.
747
748 4. **DO NOT** share the same PenFill cartridge with anyone else even if you
749 attach a new NovoFine needle for each injection. Sharing the cartridge
750 can spread disease. Each PenFill cartridge is for single-person use only.
751

752 Blood glucose levels should be tested frequently to monitor your insulin regimen.
753

754

754 **Any change in insulin should be made cautiously and only under medical
755 supervision.**

756

757

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 42

758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799

WHAT TO DO IF...

The dose indicator window does not show zero after the injection:

1. **You did not receive your full dose.**
Follow the steps on page 23 to get the remaining part of your dose.
2. **Your NovoPen Junior is malfunctioning.**
Do not use your NovoPen Junior. Contact Novo Nordisk Pharmaceuticals, Inc. at our toll free number (1-800-727-6500).

No insulin appears when you do the air shot:

1. **The piston rod is not far enough down the cartridge holder to reach the rear rubber stopper.**
Repeat the air shot (see pages 16-19).
2. **The NovoFine needle may not be securely attached.**
 - a. Put the plastic outer cap back on the NovoFine needle.
 - b. Turn the plastic outer cap in a clockwise direction to tighten the NovoFine needle.
3. **The NovoFine needle may be blocked.**
Change the NovoFine needle (see pages 14-15) and do an air shot (see pages 16-19).

The piston rod is sticking out too far to attach the cartridge holder to the barrel:

You must screw the piston rod back into the barrel (see page 7). Never try to push it in or you can damage the mechanism.

The push button will not return to zero or the piston rod will not turn back into the reset mechanism:

The return mechanism may be locked. This is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-800-727-6500) so that we may go over your technique with you.

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 43

800 **WARRANTY**

801

802 Should your NovoPen® Junior device be defective in materials or
803 workmanship within two (2) years of purchase, Novo Nordisk
804 Pharmaceuticals, Inc. will replace it at no charge if you mail the defective unit
805 along with a description of the problem and the sales receipt or other proof of
806 purchase to:

807

808 **Novo Nordisk Pharmaceuticals, Inc.**

809 **Product Safety**

810 **100 College Road West**

811 **Princeton, NJ 08540**

812

813 Protected by U.S. Patent Nos. 5,693,027; 5,626,566; 6,126,646 and Des.
814 347,894 (cartridge) restricted to use with Novo Nordisk insulin cartridges and
815 Novo Nordisk pen needles.

816

817 No other warranty is made with respect to NovoPen® Junior. This warranty
818 will be invalid and Novo Nordisk A/S, Novo Nordisk Pharmaceuticals, Inc.,
819 Bristol-Myers Squibb Co., Nipro Medical Industries Ltd., and Bang & Olufsen
820 A/S cannot be held responsible in the case of defects or damages arising
821 from:

822

- 823 ▪ The use of the NovoPen® Junior with products other than PenFill 3 mL
824 cartridges and NovoFine single-use disposable needles.
- 825
- 826 ▪ The use of the NovoPen® Junior not in accordance with the instructions in
827 this booklet.
- 828
- 829 ▪ Physical damage to the NovoPen® Junior caused by neglect, misuse,
830 unauthorized repair, accident, or other breakage.

831

832

833

NDA's 19-938, 19-959, 19-991, & 20-986
NovoPen Junior Final revision
Page 44

For assistance or further information, write to:

Novo Nordisk Pharmaceuticals, Inc.

Customer Relations

100 College Road West

Princeton, NJ 08540

Or call: 1-800-727-6500

NovoPen[®], Novolin[®], NovoLog[®], PenFill[®] and NovoFine[®]
are registered trademarks of Novo Nordisk A/S

Copyright © 2000

Novo Nordisk Pharmaceuticals, Inc.

Princeton, NJ 08540

<http://www.novonordisk-us.com>

8-4252-31-003-1

Novo Nordisk™

R HUMAN

Information for the patient who uses

Novolin® R PenFill®

Regular,
Human Insulin Injection
(recombinant DNA origin)
3 mL Disposable Cartridge
(300 units per cartridge)

100 units/mL

Please read this leaflet carefully before using this product.
Please note the special directions under "PREPARING THE INJECTION".
Novolin® R PenFill® 3 mL is designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.
PenFill® cartridge is for single person use only. See Important Notes section.

Devices

→ NovoPen® Junior, and NovoPen® 3 Demi

WARNING
ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE®, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.
SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.
PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

INSULIN USE IN DIABETES
Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels. Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

TYPES OF INSULINS
Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source: they may be of beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information.
Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

PRODUCT DESCRIPTION
This package contains five (5) Novolin® R PenFill® 3 mL cartridges. Novolin® R is commonly known as Regular, Human Insulin Injection (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a clear, colorless solution which has a short duration of action. The effect of Novolin® R begins approximately ½ hour after injection. The effect is maximal between 2½ and 5 hours and ends approximately 8 hours after injection. The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.
This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

INSULIN DELIVERY SYSTEMS
These Novolin® R PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

STORAGE
Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® R PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® R PenFill® cartridges can be kept unrefrigerated for 28 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.
Never use any Novolin® R PenFill® cartridge if it becomes viscous (thickened) or cloudy; use it only if it is clear and colorless.
Never use insulin after the expiration date which is printed on the label and carton.

IMPORTANT
Failure to comply with the following antiseptic measures may lead to infections at the injection site.
- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

PREPARING THE INJECTION
Place a NovoFine® single-use needle on the device. Refer to the instruction manual for your insulin delivery device.
Insulin PenFill® cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection. Directions for performing an air shot are provided in your insulin delivery device instruction manual.

GIVING THE INJECTION

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button all the way in to inject insulin beneath the skin. To ensure that all the insulin is injected, keep the needle in the skin for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your Insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - do not rub.

Note: Use the injection technique recommended by your physician.

USAGE IN PREGNANCY

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

INSULIN REACTION AND SHOCK

Insulin reaction "hypoglycemia" occurs when the blood glucose falls very low. This can happen if you take too much insulin, miss or delay a meal, exercise more than usual or work too hard without eating, or become ill (especially with vomiting or fever). Hypoglycemia can also happen if you combine insulin therapy and other medications that lower blood glucose, such as oral antidiabetic agents or other prescription and over-the-counter drugs. The first symptoms of an insulin reaction usually come on suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid heartbeat, or nausea. Personality change or confusion may also occur. If you drink or eat something right away (a glass of milk or orange juice, or several sugar candies), you can often stop the progression of symptoms. If symptoms persist, call your physician - an insulin reaction can lead to unconsciousness. If a reaction results in loss of consciousness, emergency medical care should be obtained immediately. If you have had repeated reactions or if an insulin reaction has led to a loss of consciousness, contact your physician. Severe hypoglycemia can result in temporary or permanent impairment of brain function and death.

In certain cases, the nature and intensity of the warning symptoms of hypoglycemia may change. A few patients have reported that after being transferred to human insulin, the early warning symptoms of hypoglycemia were less pronounced than they had been with animal-source insulin.

DIABETIC KETOACIDOSIS AND COMA

Diabetic ketoacidosis may develop if your body has too little insulin. The most common causes are acute illness or infection or failure to take enough insulin by injection. If you are ill you should check your urine for ketones. The symptoms of diabetic ketoacidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst and loss of appetite. Notify your physician right away if the urine test is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy breathing and rapid pulse are more severe symptoms and you should have medical attention right away. Severe, sustained hyperglycemia may result in diabetic coma and death.

ADVERSE REACTIONS

A few people with diabetes develop red, swollen and itchy skin where the insulin has been injected. This is called a "local reaction" and it may occur if the injection is not properly made, if the skin is sensitive to the cleansing solution, or if you are allergic to the insulin being used. If you have a local reaction, tell your physician. Generalized insulin allergy occurs rarely, but when it does it may cause a serious reaction, including skin rash over the body, shortness of breath, fast pulse, sweating, and a drop in blood pressure. If any of these symptoms develop, you should seek emergency medical care. If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or breathing difficulties) you should be skin-tested with each new insulin preparation before it is used.

IMPORTANT NOTES

1. A change in the type, strength, species or purity of insulin could require a dosage adjustment. Any change in insulin should be made under medical supervision.
2. To avoid possible transmission of disease, PenFill cartridge is for single person use only.
3. Before use, check that the PenFill cartridge is intact (e.g. no cracks). Do not use if any damage is seen, or if the part of the rubber piston that you see is wider than the white bar code band.
4. You may have learned how to test your urine or your blood for glucose. It is important to do these tests regularly and to record the results for review with your physician or nurse educator.
5. If you have an acute illness, especially with vomiting or fever, continue taking your insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland foods. Test your urine for glucose and ketones and, if possible, test your blood glucose. Note the results and contact your physician for possible insulin dose adjustment. If you have severe and prolonged vomiting, seek emergency medical care.
6. You should always carry identification which states that you have diabetes.
7. Always ask your physician or pharmacist before taking any drug.
8. Do not try to refill a PenFill cartridge.

Always consult your physician if you have any questions about your condition or the use of insulin.

Helpful information for people with diabetes is published by American Diabetes Association, 1680 Duke Street, Alexandria, VA 22314

For information contact:
Novo Nordisk Pharmaceuticals, Inc.
100 Overlook Center
Suite 200
Princeton, NJ 08540
1-800-727-6500

Manufactured by
Novo Nordisk Pharmaceutical Industries, Inc.
Clayton, NC 27520

License under U.S. Patent No. 5,462,535 and
Des. 347,894 restricted to use with Novo Nordisk
insulin delivery devices and Novo Nordisk pen needles.

Novo Nordisk™, Novolin®, PenFill®, NovoPen® and NovoFine®
are trademarks owned by Novo Nordisk A/S
Printed in USA

NovoPen® Junior, and NovoPen® 3 Demi

Date of issue: February 2000

Novo Nordisk™

N HUMAN

Information for the patient who uses

Novolin® N PenFill®

NPH, Human Insulin Isophane Suspension
(recombinant DNA origin)
3 mL Disposable Cartridge
(300 units per cartridge)

33263

100 units/mL

Please read this leaflet carefully before using this product.
Please note the special directions under "PREPARING THE INJECTION".
Novolin® N PenFill® 3 mL is designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.
PenFill® cartridge is for single person use only. See Important Notes section.

NovoPen® Junior, and NovoPen® 3 Demi

Devices

WARNING

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE®, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.
SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.
PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

INSULIN USE IN DIABETES

Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels.
Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

TYPES OF INSULINS

Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source; they may be of beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information.

Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

PRODUCT DESCRIPTION

This package contains five (5) Novolin® N PenFill® 3 mL cartridges. Novolin® N is commonly known as NPH, Human Insulin Isophane Suspension (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a cloudy or milky suspension of human insulin with protamine and zinc. The insulin substance (the cloudy material) settles at the bottom of the cartridge, therefore, the cartridge must be rotated up and down as described under "PREPARING THE INJECTION" so that the contents are uniformly mixed before a dose is given. Novolin® N has an intermediate duration of action. The effect of Novolin® N begins approximately 1½ hours after injection. The effect is maximal between 4 and approximately 12 hours. The full duration of action may last up to 24 hours after injection.

The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.

This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

INSULIN DELIVERY SYSTEMS

These Novolin® N PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

STORAGE

Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® N PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® N PenFill® cartridges can be kept unrefrigerated for 14 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.
Never use any Novolin® N PenFill® cartridge if the precipitate (the white deposit) has become lumpy or granular in appearance or has formed a deposit of solid particles on the wall of the cartridge. This insulin should not be used if the liquid in the cartridge remains clear after it has been mixed.

Never use insulin after the expiration date which is printed on the label and carton.

IMPORTANT

Failure to comply with the following antiseptic measures may lead to infections at the injection site.

- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

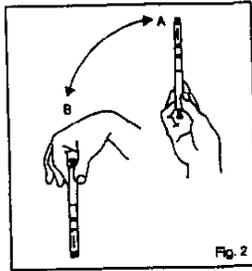
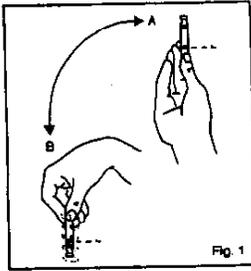
PREPARING THE INJECTION

Never place a single-use needle on your insulin delivery device until you are ready to give an injection, and remove it immediately after each injection. If the needle is not removed, some liquid may be expelled from the cartridge causing a change in the insulin concentration (strength).

The cloudy material in an insulin suspension will settle to the bottom of the cartridge, so the contents must be mixed before injection. These Novolin® PenFill® cartridges contain a glass ball to aid mixing.

When using a new cartridge, turn the cartridge up and down between positions A and B - See Figure 1. Do this at least 10 times until the liquid appears uniformly white and cloudy. Assemble your insulin delivery device following the directions in your instruction manual. For subsequent injections when a cartridge is already in the device, turn the device up and down between positions A and B - See Figure 2. Do this at least 10 times until the liquid appears uniformly white and cloudy. Follow the directions in your insulin delivery device instruction manual.

0274-31-087-1



Note: Never initiate a new injection unless there is sufficient insulin in the cartridge to ensure proper mixing (the glass ball needs adequate room for movement to mix the suspension). Insulin PenFill cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection. Directions for performing an air shot are provided in your delivery device instruction manual.

GIVING THE INJECTION

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button all the way in to inject insulin beneath the skin. To ensure that all the insulin is injected, keep the needle in the skin for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your Insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - do not rub.

Note: Use the injection technique recommended by your physician.

USAGE IN PREGNANCY

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

INSULIN REACTION AND SHOCK

Insulin reaction (hypoglycemia) occurs when the blood glucose falls very low. This can happen if you take too much insulin, miss or delay a meal, exercise more than usual or work too hard without eating, or become ill (especially with vomiting or fever). Hypoglycemia can also happen if you combine insulin therapy and other medications that lower blood glucose, such as oral antidiabetic agents or other prescription and over-the-counter drugs. The first symptoms of an insulin reaction usually come on suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid heartbeat, or nausea. Personality change or confusion may also occur. If you drink or eat something right away (a glass of milk or orange juice, or several sugar candies), you can often stop the progression of symptoms. If symptoms persist, call your physician - an insulin reaction can lead to unconsciousness. If a reaction results in loss of consciousness, emergency medical care should be obtained immediately. If you have had repeated reactions or if an insulin reaction has led to a loss of consciousness, contact your physician. Severe hypoglycemia can result in temporary or permanent impairment of brain function and death. In certain cases, the nature and intensity of the warning symptoms of hypoglycemia may change. A few patients have reported that after being transferred to human insulin, the early warning symptoms of hypoglycemia were less pronounced than they had been with animal-source insulin.

DIABETIC KETOACIDOSIS AND COMA

Diabetic ketoacidosis may develop if your body has too little insulin. The most common causes are acute illness or infection or failure to take enough insulin by injection. If you are ill you should check your urine for ketones. The symptoms of diabetic ketoacidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst and loss of appetite. Notify your physician right away if the urine test is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy breathing and rapid pulse are more severe symptoms and you should have medical attention right away. Severe, sustained hyperglycemia may result in diabetic coma and death.

ADVERSE REACTIONS

A few people with diabetes develop red, swollen and itchy skin where the insulin has been injected. This is called a "local reaction" and it may occur if the injection is not properly made, if the skin is sensitive to the cleansing solution, or if you are allergic to the insulin being used. If you have a local reaction, tell your physician. Generalized insulin allergy occurs rarely, but when it does it may cause a serious reaction, including skin rash over the body, shortness of breath, fast pulse, sweating, and a drop in blood pressure. If any of these symptoms develop, you should seek emergency medical care. If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or breathing difficulties) you should be skin-tested with each new insulin preparation before it is used.

IMPORTANT NOTES

1. A change in the type, strength, species or purity of insulin could require a dosage adjustment. Any change in insulin should be made under medical supervision.
2. To avoid possible transmission of disease, PenFill cartridge is for single person use only.
3. Before use, check that the PenFill cartridge is intact (e.g., no cracks). Do not use if any damage is seen, or if the part of the rubber piston that you see is wider than the white bar code band.
4. You may have learned how to test your urine or your blood for glucose. It is important to do these tests regularly and to record the results for review with your physician or nurse educator.
5. If you have an acute illness, especially with vomiting or fever, continue taking your insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland foods. Test your urine for glucose and ketones and, if possible, test your blood glucose. Note the results and contact your physician for possible insulin dose adjustment. If you have severe and prolonged vomiting, seek emergency medical care.
6. You should always carry identification which states that you have diabetes.
7. Always ask your physician or pharmacist before taking any drug.
8. Do not try to refill a PenFill cartridge.

Always consult your physician if you have any questions about your condition or the use of insulin.

Helpful information for people with diabetes is published by American Diabetes Association, 1660 Duke Street, Alexandria, VA 22314

For information contact:
Novo Nordisk Pharmaceuticals, Inc.
100 Overlook Center
Suite 200
Princeton, NJ 08540
1-800-727-6500

Manufactured by
Novo Nordisk Pharmaceutical Industries, Inc.
Clayton, NC 27520

License under U.S. Patent No. 5,462,535 and
Des. 347,894 restricted to use with Novo Nordisk
insulin delivery devices and Novo Nordisk pen needles.

Novo Nordisk™, Novolin, PenFill, NovoPen, NovoPen® 3 Demi
are trademarks owned by Novo Nordisk A/S

Printed in USA

Date of issue: February 2000

NovoPen® Junior, and NovoPen® 3 Demi

Novo Nordisk™

70/30 HUMAN

Information for the patient who uses

Novolin® 70/30 PenFill®

70% NPH, Human Insulin Isophane Suspension and
30% Regular, Human Insulin Injection
(recombinant DNA origin)
3 mL Disposable Cartridge
(300 units per cartridge)

100 units/mL

Please read this leaflet carefully before using this product.

Please note the special directions under "PREPARING THE INJECTION".

Novolin® 70/30 PenFill® 3 mL is designed for use with NovoPen® 3 Insulin
Delivery Device and NovoFine® disposable needles or other products
specifically recommended by Novo Nordisk.

PenFill® cartridge is for single person use only. See Important Notes section.

WARNING

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND (MANUFACTURER), TYPE (REGULAR, NPH, LENTE, ETC.), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE (RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN DOSAGE.

SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY MONITORED.

PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND "DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA (LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).

INSULIN USE IN DIABETES

Your physician has explained that you have diabetes and that your treatment involves injections of insulin or insulin therapy combined with an oral antidiabetic medicine. Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose (a simple sugar made from digested food) is trapped in the bloodstream and cannot enter the cells of the body. Some patients who don't make enough of their own insulin, or who cannot use the insulin they do make properly, must take insulin by injection in order to control their blood glucose levels.

Each case of diabetes is different and requires direct and continued medical supervision. Your physician has told you the type, strength and amount of insulin you should use and the time(s) at which you should inject it, and has also discussed with you a diet and exercise schedule. You should contact your physician if you experience any difficulties or if you have questions.

TYPES OF INSULINS

Standard and purified animal insulins as well as human insulins are available. Standard and purified insulins differ in their degree of purification and content of noninsulin material. Standard and purified insulins also vary in species source: they may be of beef, pork, or mixed beef and pork origin. Human Insulin is identical in structure to the insulin produced by the human pancreas, and thus differs from animal insulins. Insulins vary in time of action; see PRODUCT DESCRIPTION for additional information. Your physician has prescribed the insulin that is right for you; be sure you have purchased the correct insulin and check it carefully before you use it.

PRODUCT DESCRIPTION

This package contains five (5) Novolin® 70/30 PenFill® 3 mL cartridges. Novolin® 70/30 is a mixture of 70% NPH, Human Insulin Isophane Suspension (recombinant DNA origin) and 30% Regular, Human Insulin Injection (recombinant DNA origin). The concentration of this product is 100 units of insulin per milliliter. It is a cloudy or milky suspension of human insulin with protamine and zinc. The insulin substance (the cloudy material) settles at the bottom of the cartridge, therefore, the cartridge must be rotated up and down as described under "PREPARING THE INJECTION" so that the contents are uniformly mixed before a dose is given. Novolin® 70/30 has an intermediate duration of action. The effect of Novolin® 70/30 begins approximately ½ hour after injection. The effect is maximal between 2 and approximately 12 hours. The full duration of action may last up to 24 hours after injection.

The time course of action of any insulin may vary considerably in different individuals, or at different times in the same individual. Because of this variation, the time periods listed here should be considered as general guidelines only.

This human insulin (recombinant DNA origin) is structurally identical to the insulin produced by the human pancreas. This human insulin is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production organism.

INSULIN DELIVERY SYSTEMS

These Novolin® 70/30 PenFill® 3 mL cartridges are designed for use with NovoPen® 3 Insulin Delivery Device and NovoFine® disposable needles or other products specifically recommended by Novo Nordisk.

STORAGE

Insulin should be stored in a cold place, preferably in a refrigerator, but not in the freezing compartment. Do not let it freeze. Keep Novolin® 70/30 PenFill® cartridges in the carton so that they will stay clean and protected from light. Novolin® 70/30 PenFill® cartridges can be kept unrefrigerated for 10 days. Unrefrigerated cartridges must be used within this time period or discarded. Be sure to protect cartridges from sunlight and extreme heat or cold.

Never use any Novolin® 70/30 PenFill® cartridge if the precipitate (the white deposit) has become lumpy or granular in appearance or has formed a deposit of solid particles on the wall of the cartridge. This insulin should not be used if the liquid in the cartridge remains clear after it has been mixed.

Never use insulin after the expiration date which is printed on the label and carton.

IMPORTANT

Failure to comply with the following antiseptic measures may lead to infections at the injection site.

- Disposable needles are for single use; they should be used only once and destroyed.
- Clean your hands and the injection site with soap and water or with alcohol.
- Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

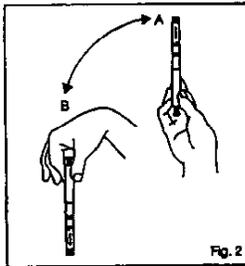
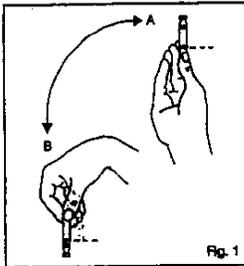
PREPARING THE INJECTION

Never place a single-use needle on your insulin delivery device until you are ready to give an injection, and remove it immediately after each injection. If the needle is not removed, some liquid may be expelled from the cartridge causing a change in the insulin concentration (strength).

The cloudy material in an insulin suspension will settle to the bottom of the cartridge, so the contents must be mixed before injection. These Novolin® PenFill® cartridges contain a glass ball to aid mixing. When using a new cartridge, turn the cartridge up and down between positions A and B - See Figure 1. Do this at least 10 times until the liquid appears uniformly white and cloudy. Assemble your insulin delivery device following the directions in your instruction manual. For subsequent injections when a cartridge is already in the device, turn the device up and down between positions A and B - See Figure 2. Do this at least 10 times until the liquid appears uniformly white and cloudy. Follow the directions in your insulin delivery device instruction manual.

Devices

NovoPen® Junior, and NovoPen® 3 Demi



Note: Never initiate a new injection unless there is sufficient insulin in the cartridge to ensure proper mixing (the glass ball needs adequate room for movement to mix the suspension). Insulin PenFill cartridges may contain a small amount of air. To prevent an injection of air and make certain insulin is delivered, an air shot must be done before each injection. Directions for performing an air shot are provided in your insulin delivery device instruction manual.

GIVING THE INJECTION

1. The following areas are suitable for subcutaneous insulin injection: thighs, upper arms, buttocks, abdomen. Do not change areas without consulting your physician. The actual point of injection should be changed each time; injection sites should be about an inch apart.
2. The injection site should be clean and dry. Pinch up skin area to be injected and hold it firmly.
3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-up area.
4. Release the skin and push the push-button all the way in to inject insulin beneath the skin. To ensure that all the insulin is injected, keep the needle in the skin for several seconds after injection with your thumb on the push button. Do not inject into a muscle unless your physician has advised it. You should never inject insulin into a vein. Follow the directions for use of your insulin Delivery Device.
5. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for a few seconds - do not rub.

Note: Use the injection technique recommended by your physician.

USAGE IN PREGNANCY

It is particularly important to maintain good control of your diabetes during pregnancy and special attention must be paid to your diet, exercise and insulin regimens. If you are pregnant or nursing a baby, consult your physician or nurse educator.

INSULIN REACTION AND SHOCK

Insulin reaction "hypoglycemia" occurs when the blood glucose falls very low. This can happen if you take too much insulin, miss or delay a meal, exercise more than usual or work too hard without eating, or become ill (especially with vomiting or fever). Hypoglycemia can also happen if you combine insulin therapy and other medications that lower blood glucose, such as oral antidiabetic agents or other prescription and over-the-counter drugs. The first symptoms of an insulin reaction usually come on suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid heartbeat, or nausea. Personality change or confusion may also occur. If you drink or eat something right away (a glass of milk or orange juice, or several sugar candies), you can often stop the progression of symptoms. If symptoms persist, call your physician - an insulin reaction can lead to unconsciousness. If a reaction results in loss of consciousness, emergency medical care should be obtained immediately. If you have had repeated reactions or if an insulin reaction has led to a loss of consciousness, contact your physician. Severe hypoglycemia can result in temporary or permanent impairment of brain function and death.

In certain cases, the nature and intensity of the warning symptoms of hypoglycemia may change. A few patients have reported that after being transferred to human insulin, the early warning symptoms of hypoglycemia were less pronounced than they had been with animal-source insulin.

DIABETIC KETOACIDOSIS AND COMA

Diabetic ketoacidosis may develop if your body has too little insulin. The most common causes are acute illness or infection or failure to take enough insulin by injection. If you are ill you should check your urine for ketones. The symptoms of diabetic ketoacidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst and loss of appetite. Notify your physician right away if the urine test is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy breathing and rapid pulse are more severe symptoms and you should have medical attention right away. Severe, sustained hyperglycemia may result in diabetic coma and death.

ADVERSE REACTIONS

A few people with diabetes develop red, swollen and itchy skin where the insulin has been injected. This is called a "local reaction" and it may occur if the injection is not properly made. If the skin is sensitive to the cleansing solution, or if you are allergic to the insulin being used, if you have a local reaction, tell your physician. Generalized insulin allergy occurs rarely, but when it does it may cause a serious reaction, including skin rash over the body, shortness of breath, fast pulse, sweating, and a drop in blood pressure. If any of these symptoms develop, you should seek emergency medical care. If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or breathing difficulties) you should be skin-tested with each new insulin preparation before it is used.

IMPORTANT NOTES

1. A change in the type, strength, species or purity of insulin could require a dosage adjustment. Any change in insulin should be made under medical supervision.
2. To avoid possible transmission of disease, PenFill cartridge is for single person use only.
3. Before use, check that the PenFill cartridge is intact (e.g. no cracks). Do not use if any damage is seen, or if the part of the rubber piston that you see is wider than the white bar code band.
4. You may have learned how to test your urine or your blood for glucose. It is important to do these tests regularly and to record the results for review with your physician or nurse educator.
5. If you have an acute illness, especially with vomiting or fever, continue taking your insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland foods. Test your urine for glucose and ketones and, if possible, test your blood glucose. Note the results and contact your physician for possible insulin dose adjustment. If you have severe and prolonged vomiting, seek emergency medical care.
6. You should always carry identification which states that you have diabetes.
7. Always ask your physician or pharmacist before taking any drug.
8. Do not try to refill a PenFill cartridge.

Always consult your physician if you have any questions about your condition or the use of insulin.

Helpful information for people with diabetes is published by American Diabetes Association, 1660 Duke Street, Alexandria, VA 22314

For information contact:
Novo Nordisk Pharmaceuticals, Inc.
100 Overlook Center
Suite 200
Princeton, NJ 08540
1-800-727-6500

Manufactured by
Novo Nordisk Pharmaceutical Industries, Inc.
Clayton, NC 27520

License under U.S. Patent No. 5,462,535 and
Des. 347,894 restricted to use with Novo Nordisk
insulin delivery devices and Novo Nordisk pen needles.

Novo Nordisk™, Novolin®, PenFill®, NovoPen®, NovolinPen®, NovoFine® and Lente®
are trademarks owned by Novo Nordisk AS

Printed in USA

Date of issue: February 2000

NovoPen® Junior, and NovoPen® 3 Demi

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Orloff
4/11/02 07:24:52 PM