TRIAMCINOLONE

Nasal Spray

Package Insert

Date of Revision: 01/01/2008

Barr Laboratories, Inc.

1. INDICATIONS AND USES

1.1 Nasal Spray: Triamcinolone acetonide nasal spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 5 years of age and older.

1.2 Nasal Spray: Triamcinolone acetonide nasal spray is approved for Sanofi-Aventis U.S. Inc. in Newzealand and Australia. However, due to differences in label, the patient information for that use is not approved for this triamcinolone acetonide nasal spray labeling.

2. DOSAGE AND ADMINISTRATION

2.1 Adult and Adolescent 17 Years of Age or Elder

2.1.1 Nasal Spray: Triamcinolone acetonide nasal spray is given in a single daily dose. The recommended starting and maintenance dose is 220 mg/day as two nasal sprays in each nostril, divided between morning and evening. The dosages should be adjusted to the individual needs of the patient. The treatment should be continued for the full course of therapy as determined by the physician.

2.1.2 Adverse Events

2.1.2.1 Nasal Spray: Triamcinolone acetonide nasal spray should be administered in the absence of nasal irritants. If irritants are used (e.g., nasal decongestants), the interval between the use of the irritant and the nasal spray should be 2 hours.

2.1.2.2 Common Adverse Reactions

2.1.2.3 Nasal Spray: The use of nasal decongestants may cause drying or burning of the nasal mucosa. The patient should be advised to avoid oral decongestants for at least 2 hours after the use of nasal decongestants.

2.1.2.4 Common Adverse Reactions

2.1.2.5 Nasal Spray: The use of nasal decongestants may cause drying or burning of the nasal mucosa. The patient should be advised to avoid oral decongestants for at least 2 hours after the use of nasal decongestants.

3. DOSAGE FORMS AND STRENGTHS

3.1 Nasal Spray: Triamcinolone acetonide in each spray contains 220 mg triamcinolone acetonide in each nasal spray (65 mg/mL), and is available in a device for delivery of an aerosolized solution containing 0.03 mg triamcinolone acetonide. The bottle should be discarded when the aqueous solution has been reduced to 16 mL. The bottle should be used for 1 month after the first dispensing. If the bottle has not been used for more than 1 month, it should be discarded. (See Warnings and Precautions.)

4. CONTRAINDICATIONS

4.1 Nasal Spray: Triamcinolone acetonide nasal spray should not be administered to patients with a history of hypersensitivity to triamcinolone acetonide or any of the other ingredients of this product. (See Warnings and Precautions.)

5. WARNINGS AND PRECAUTIONS

5.1 Nasal Spray: Triamcinolone acetonide nasal spray should be administered to patients who have received adequate medical supervision. (See Warnings and Precautions.)

6. PATIENT COUNSELING INFORMATION CONTENTS

6.1 Indications and Uses

6.2 Dosage and Administration

6.3 Warnings and Precautions

6.4 Adverse Reactions

6.5 Uses in Specific Populations

6.6 Pregnancy

6.7 Nursing Mothers

6.8 Pediatric Use

6.9 Geriatric Use

7. CLINICAL PHARMACOLOGY

7.1 Description of the Drug

7.2 Mechanism of Action

7.3 Pharmacokinetics

8. NONCLINICAL TOXICOLOGY

8.1 Mutagenesis

8.2 Carcinogenesis

8.3 Impairment of Fertility

8.4 Pregnancy

8.5 Lactation

8.6 Effects in Animal Reproduction

9. USE IN SPECIFIC POPULATIONS

9.1 Pregnancy

9.2 Nursing Mothers

9.3 Pediatric Use

9.4 Geriatric Use

10. OVERDOSAGE

11. DESCRIPTION

12. CLINICAL PHARMACOLOGY

13. CLINICAL STUDIES

14. ADVERSE REACTIONS

15. USE IN SPECIFIC POPULATIONS

16. HOW SUPPLIED AND HANDLING

17. STORAGE

18. PATIENT PACKAGE INFORMATION

19. ADVERSE REACTIONS

20. OVERDOSAGE

21. INDICATIONS AND USES

22. DOSAGE AND ADMINISTRATION

23. ADMINISTRATION INFORMATION

24. PATIENT COUNSELING INFORMATION

25. CLINICAL PHARMACOLOGY

26. NONCLINICAL TOXICOLOGY

27. CLINICAL STUDIES

28. ADVERSE REACTIONS

29. USE IN SPECIFIC POPULATIONS

30. STORAGE

31. PATIENT PACKAGE INFORMATION

32. ADVERSE REACTIONS

33. OVERDOSAGE

34. INDICATIONS AND USES

35. DOSAGE AND ADMINISTRATION

36. ADMINISTRATION INFORMATION

37. PATIENT COUNSELING INFORMATION

38. CLINICAL PHARMACOLOGY

39. NONCLINICAL TOXICOLOGY

40. CLINICAL STUDIES

41. ADVERSE REACTIONS

42. USE IN SPECIFIC POPULATIONS

43. STORAGE

44. PATIENT PACKAGE INFORMATION

45. ADVERSE REACTIONS

46. OVERDOSAGE

47. INDICATIONS AND USES

48. DOSAGE AND ADMINISTRATION

49. ADMINISTRATION INFORMATION

50. PATIENT COUNSELING INFORMATION

51. CLINICAL PHARMACOLOGY

52. NONCLINICAL TOXICOLOGY

53. CLINICAL STUDIES

54. ADVERSE REACTIONS

55. USE IN SPECIFIC POPULATIONS

56. STORAGE

57. PATIENT PACKAGE INFORMATION

58. ADVERSE REACTIONS

59. OVERDOSAGE

60. INDICATIONS AND USES

61. DOSAGE AND ADMINISTRATION

62. ADMINISTRATION INFORMATION

63. PATIENT COUNSELING INFORMATION

64. CLINICAL PHARMACOLOGY

65. NONCLINICAL TOXICOLOGY

66. CLINICAL STUDIES

67. ADVERSE REACTIONS

68. USE IN SPECIFIC POPULATIONS

69. STORAGE

70. PATIENT PACKAGE INFORMATION

71. ADVERSE REACTIONS

72. OVERDOSAGE

73. INDICATIONS AND USES

74. DOSAGE AND ADMINISTRATION

75. ADMINISTRATION INFORMATION

76. PATIENT COUNSELING INFORMATION

77. CLINICAL PHARMACOLOGY

78. NONCLINICAL TOXICOLOGY

79. CLINICAL STUDIES

80. ADVERSE REACTIONS

81. USE IN SPECIFIC POPULATIONS

82. STORAGE

83. PATIENT PACKAGE INFORMATION

84. ADVERSE REACTIONS

85. OVERDOSAGE

86. INDICATIONS AND USES

87. DOSAGE AND ADMINISTRATION

88. ADMINISTRATION INFORMATION

89. PATIENT COUNSELING INFORMATION

90. CLINICAL PHARMACOLOGY

91. NONCLINICAL TOXICOLOGY

92. CLINICAL STUDIES

93. ADVERSE REACTIONS

94. USE IN SPECIFIC POPULATIONS

95. STORAGE

96. PATIENT PACKAGE INFORMATION

97. ADVERSE REACTIONS

98. OVERDOSAGE

99. INDICATIONS AND USES

100. DOSAGE AND ADMINISTRATION

101. ADMINISTRATION INFORMATION

102. PATIENT COUNSELING INFORMATION

103. CLINICAL PHARMACOLOGY

104. NONCLINICAL TOXICOLOGY

105. CLINICAL STUDIES

106. ADVERSE REACTIONS

107. USE IN SPECIFIC POPULATIONS

108. STORAGE

109. PATIENT PACKAGE INFORMATION

110. ADVERSE REACTIONS

111. OVERDOSAGE

112. INDICATIONS AND USES

113. DOSAGE AND ADMINISTRATION

114. ADMINISTRATION INFORMATION

115. PATIENT COUNSELING INFORMATION

116. CLINICAL PHARMACOLOGY

117. NONCLINICAL TOXICOLOGY

118. CLINICAL STUDIES

119. ADVERSE REACTIONS

120. USE IN SPECIFIC POPULATIONS

121. STORAGE

122. PATIENT PACKAGE INFORMATION

123. ADVERSE REACTIONS

124. OVERDOSAGE

125. INDICATIONS AND USES

126. DOSAGE AND ADMINISTRATION

127. ADMINISTRATION INFORMATION

128. PATIENT COUNSELING INFORMATION

129. CLINICAL PHARMACOLOGY

130. NONCLINICAL TOXICOLOGY

131. CLINICAL STUDIES

132. ADVERSE REACTIONS

133. USE IN SPECIFIC POPULATIONS

134. STORAGE

135. PATIENT PACKAGE INFORMATION
Spray Nozzle

How should I store Triamcinolone Acrete?
Do not freeze. If your temperature drops below 46°F (8°C) or rises above 100° F (38°C), Triamcinolone Acreate may be damaged. Discard the solution if it is subjected to freezing or overheating.

Keep Triamcinolone Acrete out of the reach of children.

General information about the safe and effective use of Triamcinolone Acrete
Before you use Triamcinolone Acrete, tell your healthcare provider if you:

What are the ingredients in Triamcinolone Acrete Nasal Spray?
Active Ingredient:
Triamcinolone acetonide (120 mcg per spray)

Inactive Ingredients:
bromobenzene, benzyl alcohol, carbomer, propylene glycol, polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

For nasal spray:
Pharmaceuticals:
Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

For nasal suspension:
Pharmaceuticals:
Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

For nasal spray:
Pharmaceuticals:
Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

For nasal suspension:
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Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

For nasal spray:
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For nasal suspension:
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Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

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For nasal suspension:
Pharmaceuticals:
Polyethylene glycol 400, purified water, red dextrose, sodium chloride, and sodium hydroxide or hydrochloric acid to adjust final pH to range of 5.0 to 5.4.

How to Inject:

Before use:

1. Insert the needle into the naso-pharyngeal region, using the scope to guide the needle in the proper direction.

2. Push the plunger to inject the medication into the naso-pharyngeal region.

3. After injection, withdraw the needle and apply a gentle pressure to the injection site to prevent bleeding.

4. Dispose of the used needle and syringe in a sharps container.

5. Wash hands thoroughly after using the needle and syringe.

How to Use:

1. Wash your hands thoroughly before using the nasal spray.

2. Remove the protective cap from the nasal spray. If your nasal spray comes with a pump, remove the pump before use.

3. Hold the spray bottle in your dominant hand and position it perpendicular to your nose.

4. Squeeze the spray bottle firmly, releasing the contents into your nostril at a comfortable distance.

5. Allow the spray to enter your nose, then close your nose and breathe in slowly through your mouth.

6. Remove the pump or aerosol can from your nose, and allow the medication to diffuse into your nasal passages.

7. Wait for the spray to be absorbed by your nasal mucosa.

8. Repeat the process for the other nostril.

9. Dispose of the used spray bottle in a sharps container.

10. Wash your hands thoroughly after using the nasal spray.

How to Store:

1. Store this solution at room temperature, between 59°F (15°C) and 86°F (30°C), and out of direct sunlight.

2. Avoid freezing the solution.

3. Do not refrigerate the solution.

4. Do not mix the solution with any other medications.

5. Do not use the solution if it has been exposed to freezing or overheating.

6. Do not use the solution after the expiration date.

7. Use the solution within 24 hours of opening the bottle.

8. Discard the solution after the expiration date.

9. Keep the solution out of the reach of children.

10. Do not share the solution with other people.

How to Discontinue Use:

1. Contact your healthcare provider to discuss the best way to discontinue use of this medication.

2. Follow the instructions provided by your healthcare provider.

3. Do not stop using this medication without consulting your healthcare provider.

4. Be sure to complete the full course of treatment, even if symptoms improve.

How to Dispose of the Solution:

1. Discard any unused solution in a sharps container.

2. Do not flush the solution down the toilet.

3. Do not pour the solution into the drain.

4. Do not dispose of the solution in the trash.

5. Follow local regulations and guidelines for proper disposal of medication.

6. Do not reuse the solution.

7. Do not share the solution with other people.

8. Do not use the solution if it has been exposed to freezing or overheating.

9. Do not store the solution at temperatures above 125°F (52°C).

10. Do not store the solution at temperatures below 32°F (0°C).

11. Do not store the solution in direct sunlight.

12. Do not mix the solution with any other medications.

13. Do not share the solution with other people.

14. Do not reuse the solution.

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