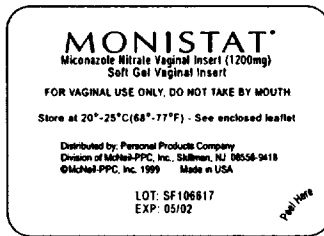


**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*


**21-308**

**APPROVED DRAFT LABELING**



Johnson & Johnson

Brand	- Monistat	File name	- Mon1ComboBlisterLabel	Design Agency Reference	- SEVEN
Category	-	Dieline No.	- n/a	Project Name	- n/a
Product Variant	- 1 Combination Pack	Barcode No. (1DIN 11g)	- n/a	Artwork program	- Illustrator 8.0
Component Type	- Blister Label	Seven Job No.	- 33845/284	Lead Mktg. Country	- USA
Consumer Unit Contents	- 1	Formulation No.	- n/a	Sales Region	- North America
Copy & Graphics Number	- XXXXXX / X	Printer	- PCI	Manufacturing Site	- n/a
GGM# / Version#	- XXXX / 3	No. of Colours	- 1	Library	- Local Market Artwork
Date	- 6/21/01	Print Method	- XXXXXX	Keywords (Market)	- XXXXXX

<p><b>Johnson &amp; Johnson</b>  <b>Family of Companies</b>          199 Grandview Road          Skillman, NJ 08558-9418          908-874-1666 (Consumer Graphics Dept. Fax)</p> <ul style="list-style-type: none"> <li>This proof indicates approximate color only!</li> <li>All colors print 100% unless otherwise indicated.</li> <li>All structure and holding lines do not print unless otherwise indicated.</li> <li>This is prepared as a color digital mechanical, no traps have been made.</li> <li>All trapping is the responsibility of the engraver and/or separator and/or printer.</li> </ul>	<p><b>ARTWORK SPECIFICS</b></p>	<p><b>Colors: 1</b>  <i>Note: All colors for reference only, printer to use pre-approved color drawdowns when printing.</i></p> <div style="text-align: center;">  <p>BLACK</p> </div> <p><b>Fonts:</b>          Optima / MathPi / Helv. Condensed          Helv. Neue / Helv. Neue Condensed          Helv. Neue Extended, Helv. Condensed-Italic, Helv. Roman</p> <p><b>Consumer</b>  <b>Graphics Manager: Bridget Motley</b>  <b>Phone: 908.874.2736</b></p>
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seven

Date of issue: 06/01/01



VAGINAL ANTIFUNGAL

Cures Most Vaginal Yeast Infections

Relieves External Vulvar Itching and Irritation Associated With a Yeast Infection

Why should I use Monistat® 1 Combination Pack?

Monistat® 1 Combination Pack is a 1-dose Soft Gel vaginal insert that cures most vaginal yeast infections, plus an external cream that can be used for relief of itching and irritation on the skin outside the vagina (vulva) due to a yeast infection. Do not use Monistat® 1 Combination Pack if this is the first time you have vaginal discharge, itching, burning and discomfort. See your doctor or health professional (GYN) to find out the cause of your symptoms. If a doctor has told you in the past that you had a vaginal yeast infection and you have the same symptoms now (such as vaginal discharge, itching or burning), then Monistat® 1 may work for you.

What is a vaginal yeast infection?

A vaginal yeast infection is a common condition caused by an overgrowth of yeast (Candida) that may normally live in the vagina. Your doctor may call this infection "monilia" or "thrush." Some women may have a yeast infection on the skin outside of the vagina (vulva) at the same time that they have a vaginal infection.

Who can get a vaginal yeast infection?

You can get a vaginal yeast infection at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, taking antibiotics, both control pills or steroids, or who have a weakened immune system are more likely to get repeated vaginal infections that may not clear up easily with proper treatment.

Some medical conditions can weaken the body's normal ability to fight infections. One of the most serious of these conditions is infection with the human immunodeficiency virus (HIV) — the virus that causes AIDS. The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections that may not clear up easily with proper treatment. If you may have been exposed to HIV and get repeated vaginal yeast infections, you should see your doctor right away. For more information on HIV infection (please contact your doctor or the CDC National AIDS Hotline). The CDC phone numbers are 1-800-342-AIDS (English), 1-800-458-5231 (Spanish) or 1-800-458-5231 (hearing impaired), TDD.

How can I tell if I have a vaginal yeast infection?

When you have a vaginal yeast infection, you may have one or more of the following symptoms:

- vaginal itching
- vaginal discharge that may be thick, white, and lumpy like cottage cheese
- vaginal soreness, irritation, or burning
- rash or redness on the skin outside the vagina (vulva)
- burning on urination
- painful vaginal intercourse (sex)

Note: Vaginal yeast infections do NOT cause fever, chills, lower abdominal, back or shoulder pain, foul-smelling vaginal discharge, or a missed period. These may be signs of a sexually transmitted disease (STD) or a tubal pregnancy. If you have these symptoms, call your doctor right away.

What are other causes of a vaginal discharge?

It is normal to have a small amount of vaginal discharge at certain times of the month. This normal discharge may be clear or slightly white and does not cause itching, pain or a foul odor.

The most common cause of an abnormal vaginal discharge is an infection. These infections include bacterial vaginosis (BV), trichomoniasis (trich), gonorrhea (GC) and/or chlamydia. All of these may be transmitted sexually and are called sexually transmitted diseases (STDs). If you have more questions about sexually transmitted diseases (STDs), call the CDC STD Hotline at 1-800-277-8622.

Although many of the infections mentioned above can cause symptoms similar to a vaginal yeast infection (vaginal discharge, itching and burning), their diagnosis must be made by a doctor so that proper treatment can be given.

If these infections are not properly treated or if proper treatment is delayed, serious problems, such as pelvic inflammatory disease (PID), may result, which may prevent you from having children in the future. If you are pregnant, and do not get the proper treatment, the infection may be passed to your baby before or during delivery and may cause you baby to have permanent damage. If you have multiple sex partners or a new sex partner, you should also ask a doctor before use to make sure you do not have an STD.

Why do women get repeated vaginal yeast infections?

Women may get repeated vaginal yeast infections that may not clear up easily with proper treatment. Listed below are some of the causes of repeated yeast infections:

- hormonal changes occurring a few days before the monthly period
- use of antibiotics
- use of some birth control pills
- pregnancy
- diabetes ("sugar" or "high blood sugar")
- clothing — wearing tight layers or moist clothing in the genital area
- weakened immune system — some drugs (such as chemotherapy or steroids) and medical conditions can weaken the body's normal ability to fight infection. One of the most serious of these conditions is infection with the human immunodeficiency virus (HIV) — the virus that causes AIDS. Infection with HIV causes the person to be more likely to get infections, including vaginal yeast infections.

If you get vaginal yeast infections often (such as once a month or 3 in 6 months), you should talk to a doctor.

Are vaginal yeast infections sexually transmitted?

Vaginal yeast infections are usually not spread by having intercourse (sex). However, if your partner has a rash, itching or discomfort in his genital area, he should contact a doctor to find out the cause of his symptoms and tell the doctor that you are treating your vaginal yeast infection with Monistat® 1 Combination Pack.

How can I prevent repeated vaginal yeast infections?

- To lower your chances of getting another yeast infection:
  - Try to keep the genital area cool and dry. Yeast grow well in warm, moist areas. The following suggestions may be helpful:
    - (1) Wear cotton underwear and loose-fitting clothes.
    - (2) Change out of damp clothes or a wet bathing suit as soon as possible.
    - (3) If you use nitraps when you are not having a menstrual period, change the nitraps often.
  - Talk with your doctor about any drugs you are now taking. You are more likely to get a vaginal yeast infection if you are taking certain drugs such as antibiotics, steroids, or birth control pills. Do not stop taking these drugs without first asking your doctor. A doctor may need to see you to make sure that you do not have other medical conditions such as diabetes or a weakened immune system.

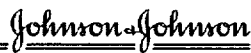
Can I use Monistat® 1 Combination Pack during my menstrual period?

Yes, this product can be used during your menstrual period. In fact, many women get vaginal yeast infections just before their period because of hormonal changes. Using Monistat® 1 Combination Pack during your period will not affect how well this product works. If you have started treatment and your period comes, you should complete the full course of treatment.

Do not use tampons while using this product, because tampons may remove some of the drug from the vagina. Use odorless-free sanitary napkins or pads instead, and change them often.

Can I use other vaginal products with Monistat® 1 Combination Pack?

- This drug should not be used with other vaginal products.
  - Douches and tampons may remove some of the Soft Gel Vaginal Insert from the vagina.
  - Spermicides may interfere with Monistat® 1 Combination Pack.
  - Condoms and diaphragms may be damaged by the product and fail to prevent pregnancy, or sexually transmitted diseases (STDs).



Brand	- Monistat	File name	- Mon1 Combination	Design Agency Reference	- SEVEN
Category	-	Display file	- n/a	Project Name	- n/a
Product Variant	- 1 Combination Pack	Barcode No. (RI Line)	- n/a	Artwork program	- Illustrator 8.0
Component Type	- Insert	Seven Job No.	- 24649736	Lead City, Country	- USA
Consumer Mail Contents	- Combo	Permutation No.	- n/a	Sales Region	- North America
Copy & Graphics Number	- 0000 / 1	Printer	- n/a	Manufacturing Site	- n/a
Color / Version	- 000 / 1	No. of Colors	- 2	Library	- Local Market Artwork
Date	- 02/01	Print Method	- screen	Keywords (Starburst)	- 00000

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**ARTWORK SPECIFICS**

Colors: 2  
Note: All colors for reference only, prior to use pre-approved color standards when printing.

Fonts:  
Optima / MathPI / Helv. Condensed  
Helv. Neue / Helv. Neue Condensed  
Helv. Neue Extended, Helv. Condensed-Ralic, Helv. Roman

Consumer  
Graphics Manager: Bridget Motley  
Phone: 800.874.2736

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**How can I get the best results when treating my infection?**

- Use the Soft Gel Vaginal Insert at bedtime, even during your menstrual period.
- Use the tube of cream externally only while symptoms are present. If you have symptoms (such as itching and irritation) on the skin outside the vagina (external), apply the cream externally 2 times a day, up to a total of 7 days, as needed.
- Dry the genital area thoroughly after a shower, bath or swim. Change out of a wet bathing suit or damp clothes as soon as possible. A dry area is less likely to lead to the overgrowth of yeast.
- Wear cotton underwear and loose-fitting clothes.
- Wipe from front to back after a bowel movement or after urination.
- Do not douche, because douching may wash the drug out of the vagina.
- Do not use tampons, because they remove some of the drug from the vagina. Use absorbent-free sanitary pads or pads as needed.
- Do not use spermicides, as they may interfere with Monistat® 1 Combination Pack.
- Do not have vaginal intercourse while using Monistat® 1 Combination Pack.
- Do not scratch the skin outside the vagina. Scratching can cause more irritation and can spread the infection.
- Tell your doctor about any drugs you are now taking. Certain drugs such as antifungals, steroids, and birth control pills, may make it more likely for you to get a vaginal yeast infection. If you are taking any of these drugs do not stop taking them without first asking a doctor.
- If you have any other medical questions or concerns about vaginal yeast infections, ask your doctor.

**What warnings should I know about when using Monistat® 1 Combination Pack?**

**For vaginal use only.**

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.

**Ask a doctor before use if you have:**

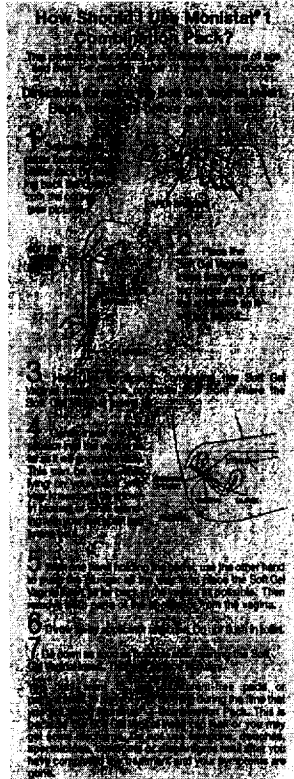
- vaginal itching and discomfort for the first time. You may need a different treatment.
- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You could have a more serious condition.
- vaginal yeast infections often (such as once a month or 2 or 3 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- born, exposure to the human immunodeficiency virus (HIV) that causes AIDS.

**Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine, warfarin (Coumadin), because bleeding or bruising may occur.**



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 Skillman, NJ 08586  
 202-686-8800 Fax: 202-686-8800

100000-00000



**When using the product:**

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STD).
- do not have vaginal intercourse.
- mild increase in vaginal burning, itching or irritation may occur.

**Stop use and ask your doctor if:**

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**What side effects may occur with Monistat® 1 Combination Pack?**

A mild increase in vaginal burning, itching, or irritation may occur when the Soft Gel Vaginal Insert is inserted. Abdominal cramping has also been reported.

Stop using Monistat® 1 Combination Pack and consult your doctor if you have abdominal pain, hives, skin rash, or if you have severe vaginal burning, itching, or irritation or swelling.

**What should I do if I have questions about Monistat® 1 Combination Pack?**

Questions of a medical nature should be taken up with your doctor. If you have any other questions or need more information on this product, call our toll-free number. Call between 8:00 AM and 5:00 PM Eastern time Monday through Friday. A nurse will gladly answer your questions. Our toll-free number is 1-877-MONISTAT (1-877-666-4782).

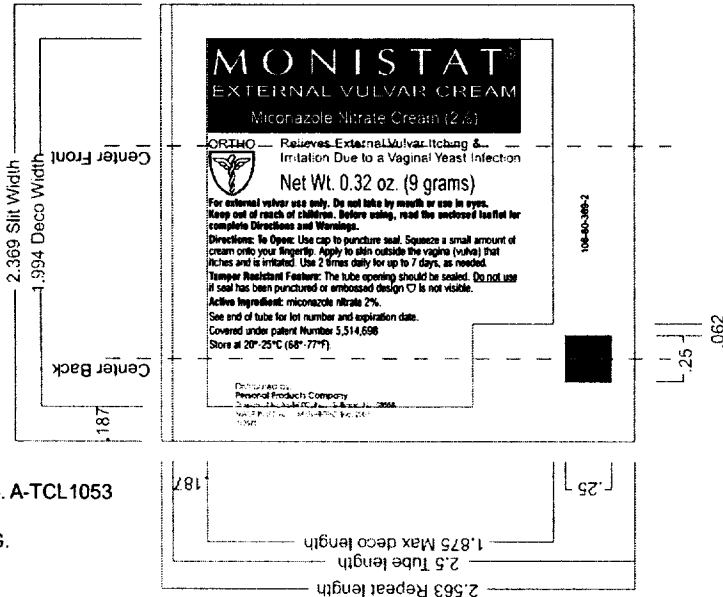
**Other information:**

- packing tray inside this carton is secured with a printed seal. Do not use if seal has been either removed or broken.
- do not use if wrapper is missing or damaged (Soft Gel Vaginal Insert is individually wrapped).
- do not use if tube seal has been punctured or embossed design (2) symbol is not visible.
- store at 20° - 25° C (68° - 77° F).

**Active ingredients:** Soft Gel Vaginal Insert: miconazole nitrate, 1200 mg. External Vaginal Cream: miconazole nitrate, 2%.  
**Inactive ingredients:** Soft Gel Vaginal Insert: gelatin, glycerin, lactose, titanium dioxide, white paraffin. External Vaginal Cream: butyric acid, isopropyl myristate, polyorbene 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.

# Artwork

## Single Language



Dieline reproduced from drawing no. A-TCL 1053  
 CCL Container Corp.  
 Title: 3/4 DIA. x 2-1/2 LG.  
 For: Ortho  
 Date 4/14/00

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<b>Brand</b>	- Monistat	<b>File name</b>	- MonExternalCrm.32ozTube	<b>Design Agency Reference</b>	- SEVEN
<b>Category</b>	- Vaginal Antifungal	<b>Dieline No.</b>	- A-TCL1053	<b>Project Name</b>	-
<b>Product Variant</b>	- External Cream	<b>Barcode No. (if applicable)</b>	- n/a	<b>Artwork program</b>	- Illustrator 8.0
<b>Component Type</b>	- Tube	<b>Seven Job No.</b>	- 33845/284	<b>Lead Mktg. Country</b>	- USA
<b>Consumer Unit Contents</b>	- 0.32oz	<b>Formulation No.</b>	- n/a	<b>Sales Region</b>	- North America
<b>Copy &amp; Graphics Number</b>	-	<b>Printer</b>	- Margo	<b>Manufacturing Site</b>	- n/a
<b>GGM# / Version#</b>	- /2	<b>No. of Colours</b>	- 3	<b>Library</b>	- Local Market Artwork
<b>Date</b>	- 6/27/01	<b>Print Method</b>	-	<b>Keywords (Market)</b>	-

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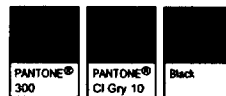
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**ARTWORK SPECIFICS**

**Colors: 3**

Note: All colors for reference only, printer to use pre-approved color drawdowns when printing.



**Fonts:** AvantGarde-Book, AvantGarde-Demi, AvantGarde-Medium, Frutiger-Black, Frutiger-Bold, Frutiger-Roman, GillSans-Bold, Helvetica, Helvetica-Bold, Helvetica-Condensed, Helvetica-Condensed-Bold, Helvetica-Narrow, Helvetica-Oblique  
**Substrate:**

**Consumer**

Graphics Manager: Bridgette Motley  
 Phone: 908.874.2736

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Date of Issue: 6/20/01

**Questions?** If you have any questions or comments, please call 1-877-466-4782

**Active Ingredients**

**Other Information**

**Directions**

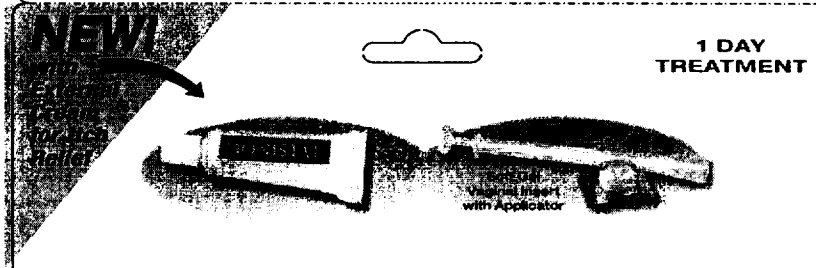
**Warnings**

**Uses**

**Drug Facts**

**Purpose**

1-DAY TREATMENT CURES MOST VAGINAL YEAST INFECTIONS



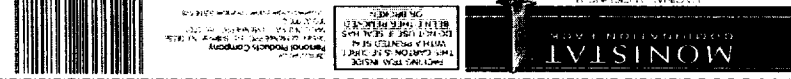
**MONISTAT**  
COMBINATION PACK  
VAGINAL ANTI-FUNGAL

2 If you have any questions or comments, please call 1-877-MONISTAT (1-877-466-4782) or visit our website at www.monistat.com

**MONISTAT**  
COMBINATION PACK  
VAGINAL ANTI-FUNGAL

1 Soft Gel Vaginal Insert With Applicator plus External Cream  
Net Wt. 0.32 oz. Insert, (9g) Tube

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Brand	MONISTAT	File name	Mon1CombCHRD
Category	VAGINAL ANTI-FUNGAL	Shiloh No.	42363
Product Variant	COMBINATION PACK	Barcode No. (4-88) 1 Bg	11885758
Component Type	OUTER CARTON	Job No.	11885758
Consumer Mail Contents	Carton	Manufacturer	North America
Copy & Graphics Number	11885758	Printer	Library
OSM# / Version	11885758	No. of Colors	4-Variable
Date	02/20/11	Print Method	offset
		Design Agency	Behrman & Son
		Project Name	Monistat 1 Combination Pack
		Artwork program	Illustrator 8.0
		Lead Billing, Country	USA
		Sales Region	North America
		Manufacturing Site	na
		Library	
		Keywords	Blattberg

Manufactured Gold is needed for rules try to create with 109 - Cool Grey 10 - 226

- FDA STANDARD SIZES for Drug Facts**
- 10 point Helvetica Bold Italic Title
  - 8 point Helvetica Bold Italic Headings
  - 6 point Helvetica Bold Subheads
  - 6 point Helvetica Regular Text
  - 6.5 point Leading
  - 2.5 point box hairline
  - 2.5 point hairline
  - 0.5 point hairline
  - 5 point ITC Zapf Dingbats Bullet

**ARTWORK SPECIFICS**

Colors: 5 + Varnish - front  
Note: All colors for reference only, please do not use unapproved color reproductions when printing

Fonts: AvantGardBook, AvantGardDem, AvantGardMed, Frutiger, FrutigerB, Helvetica, HelveticaCond, HelveticaExt, HelveticaIt, HelveticaItCond, HelveticaItExt, HelveticaItExtZapfDin

Consumer Graphics Manager: Bridgette Motley  
Phone: 968.874.2776

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**Other Information**

Keep out of reach of children. If you are taking the combination pack, please do not use any other vaginal products without your doctor's approval. If you are taking the combination pack, please do not use any other vaginal products without your doctor's approval. If you are taking the combination pack, please do not use any other vaginal products without your doctor's approval.

**Directions**

Apply the soft gel vaginal insert with applicator as directed. The applicator will insert the soft gel vaginal insert into the vagina. The applicator will insert the soft gel vaginal insert into the vagina. The applicator will insert the soft gel vaginal insert into the vagina.

**Warnings**

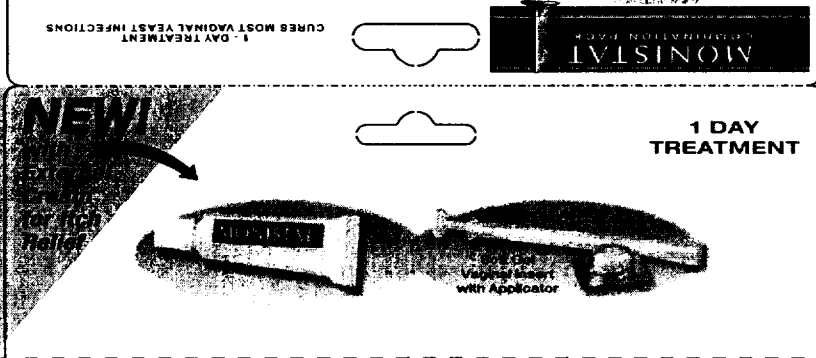
Do not use if you have never had a vaginal yeast infection diagnosed by a doctor. Do not use if you have never had a vaginal yeast infection diagnosed by a doctor. Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.

**Uses**

Relieves external itching and irritation due to vaginal yeast infection. Relieves external itching and irritation due to vaginal yeast infection. Relieves external itching and irritation due to vaginal yeast infection.

**Drug Facts**

Active ingredients: Monistat Combination Pack. Active ingredients: Monistat Combination Pack. Active ingredients: Monistat Combination Pack.



**MONISTAT COMBINATION PACK**  
VAGINAL ANTI-FUNGAL

If you have any questions or comments, please call 1-877-MONISTAT (1-877-666-4782) or visit our website at [www.monistat.com](http://www.monistat.com)

**MONISTAT COMBINATION PACK**  
VAGINAL ANTI-FUNGAL

CURES MOST VAGINAL YEAST INFECTIONS AND THE ITCHING ASSOCIATED WITH VAGINAL IRRITATION

**1 Soft Gel Vaginal Insert With Applicator plus External Cream**

Net Wt. 0.32 oz. Insert, (9g) Tube

**MONISTAT COMBINATION PACK**  
VAGINAL ANTI-FUNGAL

1 Soft Gel Vaginal Insert With Applicator plus External Cream

Net Wt. 0.32 oz. Insert, (9g) Tube

Product Information		Design Agency Reference	
Brand	MONISTAT	File name	Mon 1 Combination Pack
Category	VAGINAL ANTI-FUNGAL	Shipping No.	34300
Product Variant	COMBINATION PACK	Design No.	188188
Component Type	OUTER CARTON	Job No.	1345124
Component Unit Contents	Carton	Publication No.	Subs Region
Copy & English Number	188188	Printer	Manufacturing Site
ISBN / Version	188188	No. of Colors	4-1/4 CMYK
Size	6.25x8.5	Print Method	offset
		Language	English

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Skillman, NJ 08550-0118  
908-474-1888 (Consumer Graphics Dept. Fax)

**ARTWORK SPECIFICS**

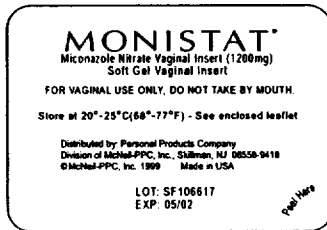
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Note: All colors for reference only. Printer to use pre-approved color alternatives when printing.

Fonts: Arial, Calibri, Cambria, Candara, Consolas, Corbel, Georgia, Helvetica, Helvetica Neue, Lucida, Segoe UI, Tahoma, Times New Roman, Verdana, Wingdings, Wingdings 2, Wingdings 3, Wingdings 4, Wingdings 5, Wingdings 6, Wingdings 7, Wingdings 8, Wingdings 9, Wingdings 10, Wingdings 11, Wingdings 12, Wingdings 13, Wingdings 14, Wingdings 15, Wingdings 16, Wingdings 17, Wingdings 18, Wingdings 19, Wingdings 20, Wingdings 21, Wingdings 22, Wingdings 23, Wingdings 24, Wingdings 25, Wingdings 26, Wingdings 27, Wingdings 28, Wingdings 29, Wingdings 30, Wingdings 31, Wingdings 32, Wingdings 33, Wingdings 34, Wingdings 35, Wingdings 36, Wingdings 37, Wingdings 38, Wingdings 39, Wingdings 40, Wingdings 41, Wingdings 42, Wingdings 43, Wingdings 44, Wingdings 45, Wingdings 46, Wingdings 47, Wingdings 48, Wingdings 49, Wingdings 50, Wingdings 51, Wingdings 52, Wingdings 53, Wingdings 54, Wingdings 55, Wingdings 56, Wingdings 57, Wingdings 58, Wingdings 59, Wingdings 60, Wingdings 61, Wingdings 62, Wingdings 63, Wingdings 64, Wingdings 65, Wingdings 66, Wingdings 67, Wingdings 68, Wingdings 69, Wingdings 70, Wingdings 71, Wingdings 72, Wingdings 73, Wingdings 74, Wingdings 75, Wingdings 76, Wingdings 77, Wingdings 78, Wingdings 79, Wingdings 80, Wingdings 81, Wingdings 82, Wingdings 83, Wingdings 84, Wingdings 85, Wingdings 86, Wingdings 87, Wingdings 88, Wingdings 89, Wingdings 90, Wingdings 91, Wingdings 92, Wingdings 93, Wingdings 94, Wingdings 95, Wingdings 96, Wingdings 97, Wingdings 98, Wingdings 99, Wingdings 100.

Consumer Graphics Manager: Bridgette Metley  
Phone: 908.874.2736



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109 - Cool Grey 10 - 226

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  - 2.5 point box hairline
  - 2.5 point hairline
  - 0.5 point hairline
  - 5 point ITC Zapf Dingbats Bullet



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Brand	- Monistat	File name	- Mon1ComboBlisterLabel	Design Agency Reference	- SEVEN
Category	-	Directive No.	- n/a	Project Name	- n/a
Product Variant	- 1 Combination Pack	Barcode No. (UPC/EAN)	- n/a	Artwork program	- Illustrator 8.0
Component Type	- Blister Label	Seven Job No.	- 33845/284	Lead Mktg. Country	- USA
Consumer Unit Contents	- 1	Formulation No.	- n/a	Sales Region	- North America
Copy & Graphics Number	- XXXXXX / X	Printer	- PCI	Manufacturing Site	- n/a
GCM# / Version#	- XXXX / 3	No. of Colours	- 1	Library	- Local Market Artwork
Date	- 6/21/01	Print Method	- XXXXXX	Keywords (Market)	- XXXXXXX

 <p><b>Family of Companies</b> 199 GrandView Road Skillman, NJ 08558-9418 908-874-1666 (Consumer Graphics Dept. Fax)</p> <ul style="list-style-type: none"> <li>This proof indicates approximate color only!</li> <li>All colors print 100% unless otherwise indicated.</li> <li>All structure and holding lines do not print unless otherwise indicated.</li> <li>This is prepared as a color digital mechanical, no traps have been made.</li> <li>All trapping is the responsibility of the engraver and/or separator and/or printer.</li> </ul>	<b>ARTWORK SPECIFICS</b>	<p><b>Colors: 1</b> Note: All colors for reference only, printer to use pre-approved color drawdowns when printing.</p> 	<p><b>Fonts:</b> Optima / MathPi / Helv. Condensed Helv. Neue / Helv. Neue Condensed Helv. Neue Extended, Helv. Condensed-Italic, Helv. Roman</p> <p><b>Consumer</b> Graphics Manager: Bridget Motley Phone: 908.874.2736</p>
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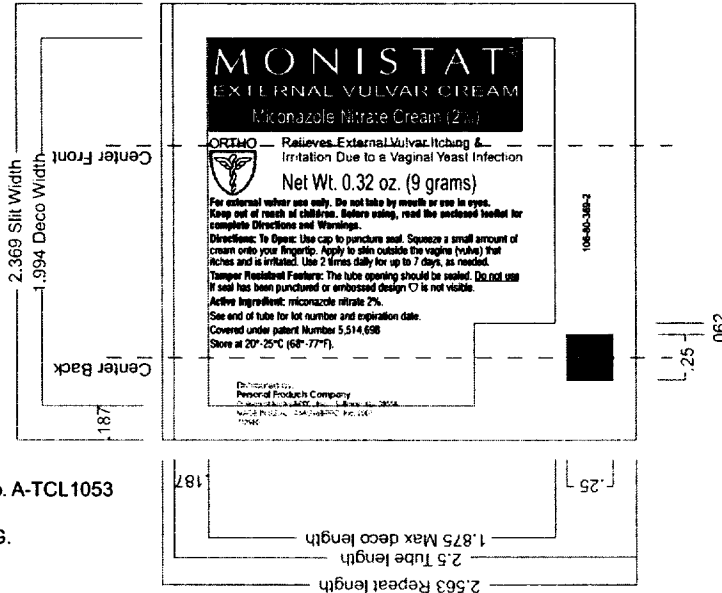
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seven Date of Issue: 0/00/01



# Artwork

## Single Language



Dieline reproduced from drawing no. A-TCL1053  
 CCL Container Corp.  
 Title: 3/4 DIA. x 2-1/2 LG.  
 For: Ortho  
 Date 4/14/00

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Brand	- Monistat	File name	- MonExternalCrm.32ozTube	Design Agency Reference	- SEVEN
Category	- Vaginal Antifungal	Dieline No.	- A-TCL1053	Project Name	-
Product Variant	- External Cream	Barcode No. (1 DIM 4 line)	- n/a	Artwork program	- Illustrator 8.0
Component Type	- Tube	Seven Job No.	- 33845/284	Lead Mktg. Country	- USA
Consumer Unit Contents	- 0.32oz	Formulation No.	- n/a	Sales Region	- North America
Copy & Graphics Number	-	Printer	- Margo	Manufacturing Site	- n/a
GGM# / Version#	- /2	No. of Colours	- 3	Library	- Local Market Artwork
Date	- 6/27/01	Print Method	-	Keywords (Market)	-

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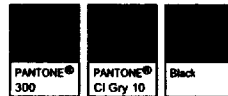
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 Skillman, NJ 08558-9418  
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**ARTWORK SPECIFICS**

**Colors: 3**

Note: All colors for reference only, printer to use pre-approved color drawdowns when printing.



**Fonts:** AvantGarde-Book, AvantGarde-Demi, AvantGarde-Medium, Frutiger-Black, Frutiger-Bold, Frutiger-Roman, GillSans-Bold, Helvetica, Helvetica-Bold, Helvetica-Condensed, Helvetica-Condensed-Bold, Helvetica-Narrow, Helvetica-Oblique  
**Substrate:**

**Consumer**  
**Graphics Manager: Bridgette Motley**  
**Phone: 908.874.2736**

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Date of Issue: 0/00/01

Consumer Information Leaflet



VAGINAL ANTIFUNGAL

Cures Most Vaginal Yeast Infections

Relieves External Vulvar Itching and Irritation Associated With a Yeast Infection

Why should I use Monistat® 1 Combination Pack?

Monistat® 1 Combination Pack is a 1-dose Soft Gel Vaginal Insert that cures most vaginal yeast infections, plus an external cream that can be used for relief of itching and irritation on the skin outside the vagina (relief due to yeast infection). Do not use Monistat® 1 Combination Pack if this is the first time you have vaginal discharge, itching, burning and discomfort. See your doctor or health professional **first** to find out the cause of your symptoms. If a doctor has told you in the past that you had a vaginal yeast infection and you have the same symptoms now, such as vaginal discharge, itching or burning, then Monistat® 1 may work for you.

What is a vaginal yeast infection?

A vaginal yeast infection is a common condition caused by an overgrowth of yeast (Candida) that may normally live in the vagina. Your doctor may call this infection "monilial" or "thrush". Some women may have a yeast infection on the skin outside of the vagina (often at the same time that they have a vaginal infection).

Who can get a vaginal yeast infection?

You can get a vaginal yeast infection at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, taking antibiotics, birth control pills or steroids, or who have a weakened immune system are more likely to get repeated yeast infections that may not clear up easily with proper treatment.

Some medical conditions can weaken the body's normal ability to fight infection. One of the most serious of these conditions is infection with the human immunodeficiency virus (HIV - the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections that may not clear up easily with proper treatment. If you may have been exposed to HIV and get repeated vaginal yeast infections, you should see your doctor right away. For more information on HIV infection please contact your doctor or the CDC National AIDS Hotline. The CDC phone numbers are 1-800-342-AIDS (English), 1-800-344-7432 (Spanish) or 1-800-243-8689 (hearing impaired, TDD).

How can I tell if I have a vaginal yeast infection?

When you have a vaginal yeast infection, you may have one or more of the following symptoms:

- vaginal itching
- vaginal discharge that may be thick, white, and lumpy like cottage cheese
- vaginal soreness, irritation, or burning
- rash or redness on the skin outside the vagina (often) during or after sex
- painful vaginal intercourse

**Note: Vaginal yeast infections do NOT cause fever, chills, lower abdominal, back or shoulder pain, foul-smelling vaginal discharge, or a missed period. These may be signs of a sexually transmitted disease (STD) or a tubal pregnancy. If you have these symptoms, call your doctor right away.**

What are other causes of a vaginal discharge?

It is normal to have a small amount of vaginal discharge at certain times of the month. This normal discharge may be clear or slightly white and does not cause itching, pain or a foul odor.

The most common cause of an abnormal vaginal discharge is an infection. These infections include bacterial vaginosis (BV), trichomoniasis (trich), gonorrhea (GC) and/or chlamydia. All of these may be transmitted sexually and are called sexually transmitted diseases (STDs). If you have more questions about sexually transmitted diseases (STDs) call the CDC STD Hotline at 1-800-277-8922.

Although many of the infections mentioned above can cause symptoms similar to a vaginal yeast infection (vaginal discharge, itching and sores), their diagnosis must be made by a doctor so that proper treatment can be given.

If these infections are not properly treated or if proper treatment is delayed, serious problems, such as pelvic inflammatory disease (PID), may result, which may prevent you from having children in the future. If you are pregnant, and do not get the proper treatment, the infection may be passed to your baby before or during delivery and may cause your baby to have permanent damage. If you have multiple sex partners or a new sex partner, you should also ask a doctor before use to make sure you do not have an STD.

Why do women get repeated vaginal yeast infections?

Women may get repeated vaginal yeast infections that may not clear up easily with proper treatment. Listed below are some of the causes of repeated yeast infections:

- hormonal changes occurring a few days before the menstrual period
- use of antibiotics
- use of some birth control pills
- pregnancy
- diabetes ("sugar" or "high blood sugar")
- clothing - wearing tight layers or moist clothing in the genital area
- weakened immune system - some drugs (such as chemotherapy or steroids) and medical conditions can weaken the body's normal ability to fight infection. One of the most serious of these conditions is infection with the human immunodeficiency virus (HIV - the virus that causes AIDS). Infection with HIV causes the person to be more likely to get infections, including vaginal yeast infections.

If you get vaginal yeast infections often (such as once a month or 3 in 6 months), you should talk to a doctor.

Are vaginal yeast infections sexually transmitted?

Vaginal yeast infections are usually not spread by having intercourse (sex). However, if your partner has a rash, itching or discomfort in his genital area, he should contact a doctor to find out the cause of his symptoms and tell the doctor that you are treating your vaginal yeast infection with Monistat® 1 Combination Pack.

How can I prevent repeated vaginal yeast infections?

To lower your chances of getting another yeast infection:

- Try to keep the genital area cool and dry. Yeast grows well in warm, moist areas. The following suggestions may be helpful: (1) Wear cotton underwear and loose-fitting clothes. (2) Change out of damp clothes or a wet bathing suit as soon as possible. (3) If you use tampons when you are not having a menstrual period, change the tampons often.
- Talk with your doctor about any drugs you are now taking. You are more likely to get a vaginal yeast infection if you are taking certain drugs such as antibiotics, steroids, or birth control pills. Do not stop taking these drugs without first asking your doctor. A doctor may need to see you to make sure that you do not have other medical conditions such as diabetes or a weakened immune system.

Can I use Monistat® 1 Combination Pack during my menstrual period?

Yes, this product can be used during your menstrual period. In fact, many women get vaginal yeast infections just before their period because of hormonal changes. Using Monistat® 1 Combination Pack during your period will not affect how well this product works. If you have started treatment and your period occurs, you should complete the full course of treatment.

Do not use tampons while using this product, because tampons may remove some of the drug from the vagina. Use pad rather than sanitary napkins or pads ahead, and change them often.

Can I use other vaginal products with Monistat® 1 Combination Pack?

- This drug should not be used with other vaginal products.
- Doushers and tampons may remove some of the Soft Gel Vaginal Insert from the vagina.
- Spermicides may interfere with Monistat® 1 Combination Pack.
- Condoms and diaphragms may be damaged by this product and fail to prevent pregnancy or sexually transmitted diseases (STDs).



Brand	- Monistat	Pile name	- Mon1 Combination	Design Agency Reference	- SEVM
Category	-	Shelf No.	- n/a	Project Name	- n/a
Product Variant	- 1 Combination Pack	Barcode No. / 881481	- n/a	Artwork program	- Illustrator 6.0
Component Type	- Insert	Seven Job No.	- 34499236	Lead Mktg. Country	- USA
Consumer Mail Contacts	- Combo	Permutation No.	- n/a	Sales Region	- North America
Copy & Graphics Number	- 00001 / 1	Printer	- n/a	Manufacturing Site	- n/a
GSN / Version	- 0001 / 4	No. of Colours	- 2	Library	- Local Market Artwork
Date	- 02/01	Print Method	- 00002	Keywords (Barcodes)	- 00000

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**ARTWORK SPECIFICS**

Colors: 2  
Note: All colors for reference only; printer to use pre-approved color management printing.

Fonts:  
Optima / MathPI / Helv. Condensed  
Helv. Neue / Helv. Neue Condensed  
Helv. Neue Extended, Helv. Condensed-Italic, Helv. Roman

Consumer  
Graphics Manager: Bridget Motley  
Phone: 908.874.2736

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**How can I get the best results when treating my infection?**

- Use the Soft Gel Vaginal Insert at bedtime, even during your menstrual cycle.
- Use the tube of cream externally only while symptoms are present. If you have symptoms (such as itching and irritation) on the skin outside the vagina (external), apply the cream externally 2 times a day, up to a total of 7 days, as needed.
- Dry the genital area thoroughly after a shower, bath or swim. Change out of a wet bathing suit or damp clothes as soon as possible. A dry area is less likely to lead to the overgrowth of yeast.
- Wear cotton underwear and loose-fitting clothes.
- Wipe from front to back after a bowel movement or after urination.
- Do not douche, because douching may wash the drug out of the vagina.
- Do not use tampons, because they remove some of the drug from the vagina. Use absorbent-free sanitary napkins or pads, as needed.
- Do not use spermicides, as they may interfere with Monistat<sup>®</sup> 1 Combination Pack.
- Do not have vaginal intercourse while using Monistat<sup>®</sup> 1 Combination Pack.
- Do not scratch the skin outside the vagina. Scratching can cause more irritation and can spread the infection.
- Tell your doctor about any drugs you are now taking. Certain drugs, such as antibiotics, steroids, and birth control pills, may make it more likely for you to get a vaginal yeast infection; if you are taking any of these drugs do not stop taking them without first seeing a doctor.
- If you have any other medical questions or concerns about vaginal yeast infections, see your doctor.

**What warnings should I know about when using Monistat<sup>®</sup> 1 Combination Pack?**

**For vaginal use only.**

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.

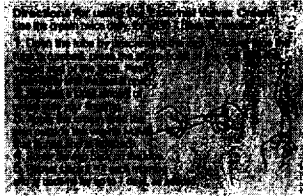
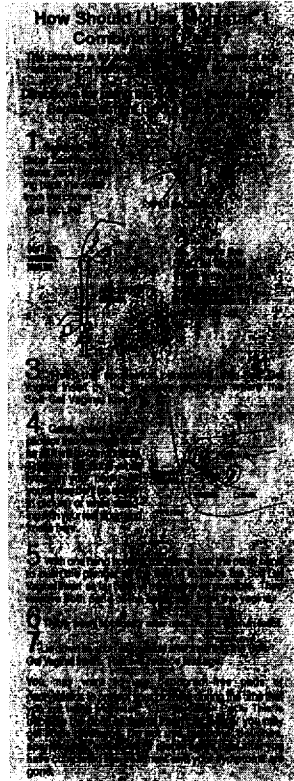
**Ask a doctor before use if you have:**

- vaginal itching and discomfort for the first time. You may need a different treatment.
- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You could have a more serious condition.
- vaginal yeast infections often (such as once a month or 2 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS.

**Ask a doctor or pharmacist before use if you are taking the following medicine, within 2 weeks before or during use:**



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**Directions for use: Soft Gel Vaginal Insert**

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse.
- mild increase in vaginal burning, itching or irritation may occur.

**Stop use and ask your doctor if:**

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.

These may be signs that this product is not working, or you may have a more serious condition or an allergic reaction.

**If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.**

**What side effects may occur with Monistat<sup>®</sup> 1 Combination Pack?**

A mild increase in vaginal burning, itching, or irritation may occur when the Soft Gel Vaginal Insert is inserted. Abdominal cramping has also been reported.

Stop using Monistat<sup>®</sup> 1 Combination Pack and consult your doctor if you have abdominal pain, fever, skin rash, or if you have severe vaginal burning, itching, or irritation or swelling.

**What should I do if I have questions about Monistat<sup>®</sup> 1 Combination Pack?**

Questions of a medical nature should be taken up with your doctor. If you have any other questions or need more information on this product, call our toll-free number. Call between 8:00 AM and 5:00 PM Eastern time, Monday through Friday. A nurse will gladly answer your questions. Our toll-free number is 1-877-MONISTAT (1-877-566-4782).

**Other Information:**

- packing may make the carton is secured with a printed seal. Do not use if seal has been either removed or broken.
- do not use if wrapper is missing or damaged. Soft Gel Vaginal Insert is individually wrapped.
- do not use if tube seal has been punctured or embossed design "O" symbol is not visible.
- store at 20° - 25° C (68° - 77° F).

**Active ingredients:** Soft Gel Vaginal Insert, miconazole nitrate, 1200 mg.

External Vaginal Cream - miconazole nitrate, 2%.  
**Inactive ingredients:** Soft Gel Vaginal Insert: gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum. External Vaginal Cream: benzoic acid, stearoyl thymosyl, polyorbital 80, potassium hydroxide, propylene glycol, purified water, stearyl alcohol.