

**PATIENT INFORMATION LEAFLET:
BIOTRIM ORAL SUSPENSION 200/40MG PER 5ML
BIOTRIM DS TABLETS 800/160MG
BIOTRIM TABLETS 400/80MG
{Cotrimoxazole}**

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Biotrim is and what it is used for
2. Before you use Biotrim.
3. How to use Biotrim.
4. Possible side effects
5. How to store Biotrim.
6. Further information

1. WHAT IS BIOTRIM AND WHAT IS IT USED FOR?

Biotrim is a combination of two antibiotics, Trimethoprim and Sulphamethoxazole which is used to treat bacterial infections in different parts of the body. It is used to treat/prevent lung infections (pneumonia/PJP). Also used to treat UTIs, respiratory tract infections, and otitis media.

Each tablet contains: Trimethoprim 80mg and Sulphamethoxazole 400mg.

Each double strength tablet: Trimethoprim 160mg and Sulphamethoxazole 800mg.

Each dispersible tablet contains: Trimethoprim 20mg and Sulphamethoxazole 100mg.

Each 5mls paediatric suspension contains: Trimethoprim 40mg and Sulphamethoxazole 200mg.

2. BEFORE YOU USE BIOTRIM:

Do not use Biotrim:

- If you have had allergy to sulphamethoxazole, trimethoprim or any of the other ingredients of this medicine.
- If you have allergy to sulfonamides
- If you have severe kidney or liver problems.
- If you have blood problems
- In infants during the first 6 weeks.

Take special care with Biotrim

- If you have severe allergies or asthma
- Skin rashes (SJS)
- If you are elderly

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines

Tell your doctor if you are taking: diuretics, blood thinners, rifampicin, HIV medicines (zidovudine, lamivudine), certain antidiabetics, immune suppressing medicines, contraceptives.

Using Biotrim with food & drink

Take with food or drink. This will stop you from feeling nauseous or having diarrhea.

Always take Biotrim tablets with lots of water.

Pregnancy and breastfeeding

Ask your doctor for advice before taking this medicine

Driving and using machines

Effects on ability to drive/operate machines have not been studied on this medicine

3. HOW TO USE BIOTRIM:

Always use Biotrim exactly as your doctor/pharmacist has told you. You should check with your doctor/pharmacist if you are not sure.

For Oral use

Tablets

General Dosage Recommendations

Adults & children more than 12years: 1 tablet (800/160) every 12 hours for 5-7days.

Or 2 tablets (400/80) every 12 hours for 5-7days.

Children below 12years:

Suspension:

6 to 12 years: two 5 ml spoonful every 12 hours

6 months to 5 years one 5 ml spoonful every 12 hours

6 weeks to 5 months one 2.5 ml spoonful every 12 hours

NB: Treatment should be continued until the patient has been symptom free for two days. The majority will require treatment for at least 5days.

If you take more Biotrim than you should

Talk to your doctor or go to a hospital straight away

If you forget to take Biotrim

Take the dose as soon as you remember. Do not take a double dose.

If you stop taking Biotrim

Keep taking your medicine until the prescribed course is finished

If you have any further questions on the use of this product, ask your doctor/pharmacist

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Biotrim can have side effects though not everyone gets them.

Allergic reactions, including urticaria, conjunctival and photosensitivity, rashes, red patches on the skin, headaches and insomnia.

Any allergic reaction on the skin should be reported immediately and drug stopped.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor/pharmacist.

5. HOW TO STORE BIOTRIM:

Keep out of reach and sight of children.

Do not use Biotrim after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Biotrim should be stored in a cool, dry place protected from direct sunlight.

Do not store above 30°C.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

The active substances in Biotrim are (Trimethoprim and Sulphamethoxazole).

What the product looks like and contents of the pack

Biotrim is available as follows:

Biotrim 400/80mg tablets: White coloured, round shaped, biconvex, bevel-edged tablets, embossed 'BIOTRIM' on one side and plain on the other.

Pack: blister packs made of PVC/aluminium foil of 10 x 10's.

Biotrim 800/160mg: Oblong, biconcave, white coloured tablets, scored and embossed BD on one side and plain on the other.

Blister pack made of PVC/aluminium foil of 10 tablets

Biotrim Suspension: Homogeneous, viscous, pink suspension with a sweet taste and vanilla flavor free from any visible impurities.

Packed in: 50mls/100mls in amber bottles with aluminium cap & package insert in a unit box.

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com.

This medicine should be used under the instructions of a doctor or pharmacist



Manufactured by:

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