

PACKAGE INSERT FOR CRYPTAZ® (NITAZOXANIDE)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What CRYPTAZ is and what it is used for
2. Before you take CRYPTAZ tablets
3. How to take CRYPTAZ tablets
4. Possible side effects
5. Storing CRYPTAZ tablets

[Name of the medicinal product]

NAME OF THE MEDICINAL PRODUCT

CRYPTAZ 500 mg tablets
nitazoxanide

[Full statement of the active substance(s) and excipient(s)]

FULL STATEMENT OF THE ACTIVE SUBSTANCE AND EXCIPIENTS

Active Substance:

Each tablet contains 500 mg of nitazoxanide.

Excipients:

Tablet core: maize starch, pregeletinized corn starch, hydroxypropyl methylcellulose, sucrose, sodium starch glycolate, talc and magnesium stearate.

Tablet coating: polyvinyl alcohol, talc, titanium dioxide, lecithin, xanthan gum, quinoline yellow lake (E104) and sunset yellow lake (E110).

[Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different]

Marketing Authorization Holder:

Laboratoria Romark, N.V., Deuzeldlaan 70, 2900 Schoten, Belgium

Manufacturing Authorization Holder:

Laboratoria Qualiphar, N.V., Rijksweg 9, 2880 Bornem, Belgium

1. WHAT CRYPTAZ IS AND WHAT IT IS USED FOR

[Pharmaceutical form and contents; pharmacotherapeutic group]

CRYPTAZ 500 mg tablets are presented as round yellow film-coated tablets in blister packs containing 6 or 14 tablets.

[Therapeutic indications]

This medicinal product is a “broad spectrum” antiparasitic agent. This means that it kills a wide variety of parasites, both protozoa and helminths, which cause infections. CRYPTAZ tablets are used in adults for the following parasitic infections:

- Intestinal protozoan infections caused by *Cryptosporidium parvum*, *Giardia intestinalis (lamblia)*, *Blastocystis hominis*, *Balantidium coli*, and *Entamoeba histolytica*.
- Helminth infections caused by common roundworms, hookworms, whipworms, dwarf tapeworms, beef tapeworms and *Fasciola hepatica*.

2. BEFORE YOU TAKE CRYPTAZ TABLETS

[List of information necessary before taking the medicinal product]

[Contraindications]

Contraindications:

Do not take CRYPTAZ tablets if you are hypersensitive (allergic) to nitazoxanide or any of the other ingredients of CRYPTAZ.

[Appropriate precautions for use; special warnings]

CRYPTAZ tablets are intended for treatment of adults and adolescents at least 12 years of age. CRYPTAZ tablets should not be given to children under 12.

[Interactions with food and drink]

Taking CRYPTAZ tablets with food and drink:

CRYPTAZ tablets should be taken with food.

[Use by pregnant or breast-feeding women]

Pregnancy or breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

[Effects on the ability to drive or to use machines]

Driving and using machines:

There have been no reports of CRYPTAZ tablets having an effect on the ability of a patient to drive and use machines. Nevertheless, patients should be aware of how they react to this medication before driving or operating machinery.

[Interaction with other medicinal products]

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO TAKE CRYPTAZ TABLETS

[Instructions for proper use]

[Dosage]

If you have the impression that the effect of CRYPTAZ is too strong or too weak, talk to your doctor or pharmacist.

[Method and/ or route(s) of administration]

CRYPTAZ tablets are to be swallowed with food.

[Frequency of administration]

The following table shows the dose, frequency of administration and duration of treatment for different infections:

Infection	Dose (oral administration)
Intestinal protozoan infections caused by <i>Cryptosporidium parvum</i> , <i>Giardia intestinalis</i> (<i>lamblia</i>), <i>Blastocystis hominis</i> , <i>Balantidium coli</i> and acute intestinal amoebiasis or amoebic dysentery caused by <i>Entamoeba histolytica</i>	One CRYPTAZ 500 mg tablet twice daily for a minimum of 14 days. <u>Best eradication efficacy for <i>B.hominis</i> obtained with 500mg CRYPTAZ tablet taken twice daily for a period of 28 days (minimum).</u>
Helminthiasis caused by <i>Ascaris lumbricoides</i> (common roundworm), hookworms such as <i>Ancylostoma duodenale</i> (common hookworm) and <i>Necator americanus</i> (American hookworm) <i>Trichuris trichiura</i> (whipworm) and <i>Hymenolepis nana</i> (dwarf tapeworm)	One CRYPTAZ 500 mg tablet twice daily for 7 days
Taeniasis caused by <i>Taenia saginata</i> (beef tapeworm)	Four CRYPTAZ 500 mg tablets as one single dose
Fascioliasis caused by <i>Fasciola hepatica</i>	One CRYPTAZ 500 mg tablet twice daily for seven days

[Duration of treatment]

[Symptoms in case of overdose and actions to be taken]

If you take more CRYPTAZ tablets than you should:

Do not take more CRYPTAZ tablets than your doctor tells you to take. If you take more tablets than you should, contact your doctor immediately.

[Actions to be taken when one or more doses have been missed]

If you forget to take a tablet:

Take it as soon as possible. If it is almost time for your next dose, skip the missed dose, and take the next tablet at the right time. Do not take a double dose to make up for forgotten individual doses.

[Indication of the risk of withdrawal effects]

4. POSSIBLE SIDE EFFECTS

[Description of side effects]

Like all medicines, CRYPTAZ can have side effects. The side effects associated with use of CRYPTAZ have been primarily limited to the gastro-intestinal tract: epigastric pain or abdominal pain, diarrhoea, nausea and vomiting. Other side effects included headache, dizziness and yellow discoloration of urine. If any of these side effects are troublesome, severe or do not wear off quickly, tell your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING CRYPTAZ TABLETS

[Storage conditions and expiry date]

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Do not use after the expiry date stated on the carton.

[Where appropriate, warning against certain visible signs of deterioration]

This leaflet was last approved on 12 July 2004

Further information

For any information about this medicinal product, please contact the local Technical Specialist at **TRI-MED Distributors** (Freecall:1800 08 05 07; Fax 08 9388 1444 : Phone: 08 9388 1744). Email; info@trimed.com.au OR visit our website on www.trimed.com.au

**A paediatric formulation of Nitazoxanide (Trade Name - Alinia® -) was US-FDA approved in 2003.
This is Available from TRI-MED Distributors.**



**TRI-MED Distributors P/L.
“HEALTH PRODUCTS FOR THE FUTURE TODAY”**

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