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### 1.5.3 Patient Information Leaflet (PIL)

#### **Package leaflet: Information for the patient**

**VERZOL® tablets 400 mg**

**VERZOL® suspension 40 mg/ml, 10 ml**

Albendazole

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

In this package leaflet:

1. WHAT VERZOL IS AND WHAT IT IS USED FOR?
2. BEFORE YOU TAKE VERZOL
3. HOW TO TAKE VERZOL?
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE VERZOL?
6. CONTENT OF THE PACK AND OTHER INFORMATION

#### **1. WHAT VERZOL IS AND WHAT IT IS USED FOR?**

VERZOL contains a medicinal substance called albendazole. This medicine is an imidazole antiparasitic. Verzol is indicated in parasitoses such as threadworms, roundworms, hookworms, whipworms, anguillulosis, taeniasis, trichinosis and giardiasis.

#### **2. BEFORE YOU TAKE VERZOL**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Do not take VERZOL in the following cases:**

- allergy to albendazole or any of the components listed in section 6.
- if you are pregnant
- if you are a woman of childbearing age not using an efficient contraception method
- if you are breast feeding.


In case of doubt, it is essential to ask the advice of your doctor or pharmacist.

#### **Warnings and precautions**

Seek the advice of your doctor or pharmacist before taking VERZOL.

Before you or your child take VERZOL, your doctor must know:

- if your child is under 6 years of age
- if you or your child have a liver disease
- if you or your child has a kidney disease

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- if you are a woman of childbearing age (see section “Pregnancy and breastfeeding”)
- if you are a man and your female partner is a woman of childbearing age (see section “Pregnancy and breastfeeding”)
- your doctor will inform you on the measures related to efficient contraception and on the potential risk in pregnancy

#### Convulsions and other symptoms

Patients treated for a parasite infection might also have, without noticing, a rare and serious infection of the brain called neurocystocercosis. The symptoms include convulsions (see section 4).

#### Blood tests and VERZOL

Because of the possibility of occurrence of disturbed blood formula or liver function during long term treatment with albendazole with high doses, as when treating trichinosis, a liver workup is required, regularly before and during the treatment. This blood workup shall be closely monitored if you have an existing liver disease or if you already had liver disorders while being treated with albendazole (see section 4).

In order to increase the efficacy of the treatment of trichinosis, the treatment should be initiated as early as possible.

In case of doubt, do not hesitate to ask the advice of your doctor or pharmacist.

#### **Other medicines and VERZOL**

You must report any other medicine you are currently taking or have taken recently, to your doctor or pharmacist even those you have received without prescription.

#### **Pregnancy**


If you are pregnant, you must not take this medicine. This medicine can cause malformation in your unborn child (embryo) (see section “Do not take VERZOL”).

#### *Woman of childbearing age and men*

Male and female patients should take special precautions during their sexual intercourses if a pregnancy can occur:

- if you are a woman of childbearing age, you should have a negative pregnancy test before starting the treatment. You should use an efficient contraceptive method during your treatment and up to 6 months after stopping the treatment. You can discuss that with your doctor.
- if you are a man, you should not have sexual intercourses with a pregnant woman without using a condom. Using a condom enables lowering your partner’s exposition to albendazole.

You or your female partner should use an efficient contraceptive method during the course of the treatment and the 3 months following stopping the treatment. You can discuss that with your doctor.

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### **Breastfeeding**

If you are a breastfeeding woman, you should not take this medicine. Stop breastfeeding before starting the treatment. In case of single intake (1 tablet at a time), breastfeeding should be stopped for the 2 days following the administration. You can discuss that with your doctor.

### **Fertility**

According to trials carried out in animal, albendazole could cause infertility in men. This can affect your ability to conceive a child.

### **Driving and using machines**

Sensations of dizziness might occur after taking this medicine. If that happens, do not drive or do not do a work that requires a high level of attention.

### **VERZOL tablet contains lactose**

This medicine should not be used by patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption.

Tablets and suspension contains an azo colouring agent (E110) that may cause allergic reactions.


### **3. HOW TO TAKE VERZOL?**

Suspension: shake the bottle or the sachet before use.

Pack : open the pack by tearing or cutting at the level of the pre-cutting line.

### **Dosage:**

Your doctor will decide of the dose and treatment duration of VERZOL that suits you or your child. This depends on your weight, your age and the type and severity of your infection.

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Indications	Daily dose	Treatment duration
<b>Intestinal and skin infections (short-term treatment with lower dose)</b>		
Oxyurosis	Children from 1 to 2 years: 5 ml suspension (200 mg) in one single dose Adults and children older than 2 years*: 400 mg, 1 single tablet or 10 ml of suspension in single dose Strict hygiene measures should be taken and family environment should also be treated.	Single dose to be repeated 7 days after.
Roundworms Hookworms Whipworms	Children from 1 to 2 years: 5 ml of suspension (200 mg) Adults and children older than 2 years*: 400 mg, 1 single tablet or 10 ml of suspension in single dose.	Single dose. *
Anguillulosis Taeniasis (associated with others parasitosis)	Adults and children older than 2 years *: 400 mg, 1 tablet or 10 ml of suspension daily	1 daily dose during 3 days. *
Giardiasis	Children older than 2 years*: 1 tablet or 10 ml of suspension daily.	1 daily dose during 5 days.
<b>Systemic infections (long-term treatment with higher doses)</b>		
Trichinosis	Children*: 15 mg/kg/day divided into two daily doses with a maximum dose of 800 mg/day Adults: 1 tablet or 10 ml of suspension twice daily	2 daily doses (morning & evening) during 10 to 15 days depending on the severity of the symptoms and on the onset of treatment.

\*particularly in case of anguillulosis, whipworm infection, taeniasis, if the worm control performed 3 weeks after the treatment is positive, a second treatment should be administered. In case of intestinal and skin infections you must talk to your doctor if you do not feel better or if you feel worse after 3 weeks.


#### Method and route of administration

Oral route.

For children under 6 years, tablet form of 400 mg is inappropriate due to wrong route risk, and only suspension form should be used.

The tablets can be swallowed with a glass of water. The treatment does not require previous fast nor purgative.

In the treatment of trichinosis, the treatment should be administered with a meal.

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**If you take more VERZOL than you should**

Immediately refer to your doctor or pharmacist.

**If you forget to take VERZOL**

Take the dose as soon as possible and take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

In case of doubt, seek the advice of your doctor or pharmacist.

**If you stop taking VERZOL**

Take VERZOL as long as your doctor has advised you to. Do not stop your treatment as long as your doctor has not told you to, even if you feel better. If you do not finish your treatment completely, the infection can relapse. It is important that you follow all your treatment with VERZOL.

It is then important that you take all your VERZOL treatment.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, VERZOL may cause side effects, although not everybody gets them:

**Severe skin reactions: ask your doctor for help immediately**

A small number of patients taking albendazole develop an allergic reaction that can transform into even more severe skin reactions, that can life-threatening is they are not treated. Symptoms of these reactions include:

- skin rash or skin reddening that can form blisters and look like small targets (central black spot surrounded by a pale zone and a dark ring around the edge) (erythema multiform)
- spread skin rash with blistering and desquamation, especially around the mouth, nose, eyes and genitalia (Stevens-Johnson syndrome).

If you notice any of these symptoms, contact your doctor immediately.

Watch the occurrence of the combination of the following symptoms:

- headaches that can be severe
- nausea and vomiting
- convulsions
- vision problems

Contact your doctor immediately if you have these effects.


**Intestines and skin infections (short-term treatment with low doses): giardiasis, oxyurosis, roundworms, hookworms, whipworms, anguillulosis and taeniasis**

**Uncommon side effects (occurring in less than 1 in 100 patients):**

- gastro-intestinal disorders (gastric or abdominal pains, nausea, vomiting and diarrhoea)
- headaches
- dizziness

**Side effects with unknown frequency**

- allergic reactions including skin rash, itching, hives

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- yellowing of the skin
- disturbed liver workup (increased liver enzymes)
- skin rash or skin reddening that can form blisters and look like small targets (central black spot surrounded by a pale zone and a dark ring around the edge) (erythema multiform)
- spread skin rash with blistering and desquamation, especially around the mouth, nose, eyes and genitalia (Stevens-Johnson syndrome).

**Systemic infection (long-term treatment with high doses): trichinosis**

**Very common side effects (occurring in more than 1 in 10 patients):**

- headaches
- disturbed liver workup (low to moderate increase in transaminases level getting back to normal when stopping the treatment)

**Common side effects (occurring in less than 1 in 10 patients):**

- dizziness
- gastro-intestinal disorders (gastric pains, nausea, vomiting)
- transient and moderate hair loss that decreases when decreasing or stopping the treatment
- isolated fever during the first days of treatment

**Uncommon side effects (occurring in less than 1 in 100 people):**

- allergic reactions including skin rash, itching, hives
- liver inflammation (hepatitis)
- decrease in the white blood cells count (leucopenia)

**Side effects of unknown frequency:**

- skin rash or skin reddening that can form blisters and look like small targets (central black spot surrounded by a pale zone and a dark ring around the edge) (erythema multiform)
- spread skin rash with blistering and desquamation, especially around the mouth, nose, eyes and genitalia (Stevens-Johnson syndrome).

If you notice any of these symptoms, contact your doctor immediately (see “Severe skin reactions” above in the section 4).


- pancytopenia: decrease in all blood cells lines (red blood cells, white blood cells and platelets) because of an impoverishment in blood elements-producing cells of the bone marrow
- significant decrease in white blood cells (leucopenia or agranulocytosis if it concerns white blood cells called neutrophils)
- inability of the bone marrow to produce red blood cells or white blood cells (medullar aplasia)

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

**5. HOW TO STORE VERZOL?**

Keep out of the sight and reach of children.

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Do not use VERZOL after the expiry date stated on the outer pack.  
Protect from heat, light and moisture, store at a temperature not exceeding 30 °C.  
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. CONTENT OF THE PACK AND OTHER INFORMATION

### What does VERZOL contain?

The active substance is albendazole (400 mg per tablet or per 10 ml suspension)

The other ingredients are:

Tablets: maize starch, lactose, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), magnesium stearate, purified talc, colloidal anhydrous silica, sunset yellow supra colour (E110).

Suspension: saccharose, sorbitol, sodium carboxymethyl cellulose, sunset yellow supra colour (E110), orange flavour, banana flavour, glycerin, sodium methylparahydroxybenzoate (E219), sodium propylparahydroxybenzoate (E217), sodium benzoate (E211), sodium saccharin, citric acid, Tween 80, purified water.

### What VERZOL looks like and contents of the pack?

This medicine is presented in the form of orange, elongated, scored tablets or in the form of orange suspension.

Tablet: Box of 1 tablet in blister pack.

Suspension: Bottle of 10 ml or sachet of 10 ml.

All packaging might not be marketed.

### VERZOL® is a registered trademark

of Exphar s.a. Zoning Industriel de Nivelles Sud, zone II – Av. Thomas Edison 105 – 1402 Thines (Belgium)

Manufacturer:

Gracure Pharmaceuticals Ltd.,

E-105 Industrial area, Phase III, Bhiwadi (Raj) INDIA.

**The last date this package leaflet was revised is 08/2018**