PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

DIATRIM Capsules

Active ingredient: Each capsule contains: Diacerein 50 mg

Inactive ingredients in the preparation - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

The medicine is not intended for children and adolescents under 15 years of age.

- The preparation is not intended for patients with liver disease or with a history of liver disease.
- While using the preparation, monitor for early signs of hepatic injury, such as: increased liver enzymes, tiredness, loss of appetite, jaundice, abdominal pain, nausea, vomiting, change in stool color combined with change in color of the urine, reduced consciousness or itching of the skin.

  In case these signs develop, stop the treatment and refer to a doctor.
- Taking Diatrim can often cause to diarrhea and consequently increase the risk of dehydration and hypokalemia.

  To reduce the risk of developing severe diarrhea:
  - It is recommended to start treatment with a lower dosage of 50 mg per day for the first 2-4 weeks of treatment with the medicine.
  - If you develop diarrhea, stop treatment with the medicine and refer to a doctor as soon as possible.
- If you are 65 years of age or older, be sure to more closely monitor side effects that may develop.

1. WHAT IS THE MEDICINE INTENDED FOR?

For symptomatic treatment of osteoarthritis.

Therapeutic group: Nonsteroidal anti-inflammatory drugs, anti-osteoarthritic.

2. BEFORE USING THE MEDICINE

X Do not use this medicine if:

- you are sensitive/allergic to the active ingredient or to any of the other ingredients contained in the medicine.
- you are sensitive to rhein, a substance found in the rhubarb plant.
- you suffer from liver disease or have a history of liver disease.
- you are suffering, or have suffered in the past, from colitis, Crohn's disease.
- you are suffering from partial/complete intestinal obstruction, or from abdominal pain with an unknown cause.

Special warnings regarding use of the medicine:

- **Before treatment with Diatrim, tell the doctor if:**

  you are suffering, or have suffered in the past, from impaired function of: the kidney/urinary system.
- it is recommended to start treatment with a lower dosage of 50 mg per day for the first 2-4 weeks of treatment with this medicine, to reduce the risk of developing severe diarrhea.
- if you are 65 years of age or older, be sure to more closely monitor side effects that may develop.
- the medicine is not intended for children and adolescents under 15 years of age.
- if you are sensitive to any food (especially to the rhubarb plant), to lactose or to any medicine, inform the doctor before taking the medicine.
- **tests that must be performed before using the medicine:** liver function test.

! If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Laxatives: do not use laxatives when taking Diatrim.
- Antacids: wait at least two hours between taking this medicine and taking antacids.
- Diuretics.
- Digoxin or other glycosides for heart treatment – due to an increase in the risk of arrhythmia as a result of the possible development of hypokalemia.

! Use of the medicine and food

Swallow the medicine with food.

! Use of the medicine and alcohol consumption

Drinking alcohol during the course of treatment with the medicine may increase the risk of hepatic damage. Therefore, it is recommended to abstain from consuming alcohol during the course of treatment with the medicine.

! Pregnancy and breastfeeding

The medicine is not recommended for use during pregnancy and when breastfeeding.

If you discover that you are pregnant and have already taken the medicine, refer to a doctor immediately.

! Important information about some of the ingredients in this medicine

The medicine contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, contact your doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about how to use it.

The dosage and treatment regimen will be determined by the doctor only.

It is recommended to start treatment with a lower dosage of 50 mg per day (in the evening) for the first 2-4 weeks of treatment with the medicine. After this period and when instructed by the doctor, the treatment dosage can be increased to 50 mg twice a day (morning and evening).

In case of kidney disease, the dosage will be halved.

Maximal pain reduction will only be felt after a few weeks. Painkillers can also be taken, as per the doctor's recommendation.

Do not exceed the recommended dose.

Do not chew! Do not open the capsule! Swallow the medicine with a glass of water, with a meal.

The medicine is not intended for children and adolescents under 15 years of age.

Tests and follow up:

When using the preparation, monitor for early signs of hepatic injury, such as: increased liver enzymes, tiredness, loss of appetite, jaundice, abdominal pains, nausea, vomiting, change in stool color combined with change in color of the urine, reduced consciousness or itching of the skin.

If these signs develop, stop the treatment and refer to a doctor.

If you accidentally took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine consult a doctor.

Adhere to the treatment regimen recommended by the doctor.

The effect of the medicine is only apparent after a few weeks.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Diatrim may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine and refer to a doctor immediately if diarrhea occurs. In certain cases, the diarrhea may be severe and lead to life-threatening complications, such as fluid loss and electrolyte imbalance.

Refer to a doctor immediately if abdominal pain, jaundice (yellowing of the whites of the eyes and skin), changes in the color of the urine (from yellow-orange to red or even brown), pigmentation of the intestinal mucosa (rare), reduced consciousness or itching of the skin occur, since these symptoms may indicate a liver disease.

Additional known side effects:

Very common side effects – effects that occur in more than one user in ten:

- Diarrhea
- Soft stools
- Abdominal pain

These effects usually pass within a short time after the adaptation period to the medicine. However, monitor for additional symptoms that may suggest hepatic injury (see above).

Common side effects – effects that occur in 1-10 users in 100:

- Frequent bowel movements
- Flatulence
- Skin effects such as: rash, itching, eczema

Uncommon side effects – effects that occur in 1-10 users in 1000:

- Increased liver enzymes in blood tests

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the online side effects reporting form that can be found on the homepage of the Ministry of Health www.health.gov.il or through the following link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/blister. The expiry date refers to the last day of that month.
- Store in a cool and dry place, below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients: Lactose (anhydrous), magnesium stearate, gelatin capsule (*Indigo carmine, erythrosine, titanium dioxide, water, gelatin*).

  Each capsule contains 240 mg lactose.
- **What does the medicine look like and what are the contents of the package?**

  Each package contains 30 dark blue and white capsules packaged in a blister.
- Manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health in November 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132.16.30996.00

0216C

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

TRIMA

101308010