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

The medicine is dispensed without a doctor's prescription

Dicloplast® Patch

Each patch contains: 180 mg Diclofenac Epolamine (equivalent to 140 mg Diclofenac Sodium)

For a list of the inactive and allergenic ingredients in the preparation - see Section 6 "Further information" and Section 2 "Important information about some of the ingredients of the medicine".

Read the 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.
Use the preparation according to the instructions in the section on dosage in this leaflet.
If you need further information, consult with the pharmacist. Refer to the doctor if signs of the disease (symptoms) worsen or do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is indicated for topical treatment of rheumatic diseases, pain and non-infectious inflammation.

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient Diclofenac or to any of the other ingredients contained in the medicine, to aspirin and salicylates, or to other NSAID preparations.
- You have breathing problems, asthma, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs.
- You have entered or are beyond your sixth month of pregnancy.
- You have an active stomach ulcer (peptic ulcer).
- You have damaged skin, including discharge, infections, eczema, burns or wounds.
- You are a child or adolescent below the age of 16 years.

❗ Special warnings regarding use of the medicine

Before treatment with Dicloplast, tell the doctor if:

- You have heart disease.
- You have kidney disease.
- You have liver disease.
- You have had stomach ulcers in the past.
- You have an inflammatory bowel disease such as: Crohn's disease or ulcerative colitis or you are susceptible to bleeding from your bowel.
- You have asthma.
- You have breathing problems, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs.
- You are taking diclofenac or other NSAIDs, as an oral or topical preparation.
- You regularly sunbathe or regularly use a sun-bed.
- You are an elderly person who may be at higher risk for side effects.
- Do not use Dicloplast on open wounds (abrasions, cuts).

❗ Children and adolescents:
The medicine is not intended for children or adolescents below the age of 16 years.

❗ Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

- Aspirin and salicylates.
- Non-steroidal anti-inflammatory preparations.

❗ Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult with the doctor or pharmacist before using the medicine.
This preparation has a possible side effect of kidney damage in the fetus and a reduction in the amount of amniotic fluid starting from Week 20 of pregnancy. It is recommended to refrain from using NSAIDs starting from Week 20 of pregnancy and to consult a healthcare practitioner if needed.
Dicloplast must not be used if you have entered or are already beyond your sixth month of pregnancy, as it could harm your fetus or cause problems at delivery. Before the sixth month of pregnancy, use Dicloplast only after receiving medical advice. Keep the dose as low as possible and the duration of treatment as short as possible.
During breastfeeding Dicloplast should be used only after receiving medical advice, as the active ingredient, diclofenac, passes into breast milk in small amounts. It is important to avoid applying Dicloplast on the breasts of nursing mothers or elsewhere on large areas of skin or for a prolonged period of time.
Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

❗ Driving and using machines:
Use of Dicloplast has no effect on the ability to drive or use machines.

❗ Important information about some of the ingredients of the medicine:
The medicine contains Propyl Parahydroxybenzoate and Methyl Parahydroxybenzoate, which may cause an allergic reaction (at times delayed), and also contains 420 mg Propylene Glycol in each patch. In addition, the medicine contains a fragrance containing the allergens Benzyl Salicylate, Cinnamyl Alcohol and Hydroxycitronellal, which may cause allergic reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation.

The usual dosage is generally:
Place a patch on the affected area in the morning and in the evening (for up to 12 hours).
Do not exceed the recommended dose.

Duration of treatment - If there is no improvement in your condition within 7 days, refer to the doctor. The duration of treatment should not exceed 14 days.
Do not use this medicine frequently or for a prolonged period without consulting the doctor.

Method of use - do not swallow. For external use only.

- Cut off the top of the inner sachet along the indicated line and open the seal.
- Record the date on which the sachet was opened in the space provided.
- Remove a patch from the sachet and close the sachet well, using the seal.
- Remove the protective clear wrapping.
- Apply the patch to the skin around the painful or swollen area. If necessary, secure the patch in place with an additional adhesive strip.
- Do not cover the patch with other dressings. Where possible, the patch can be fixed in place using the elastic tubular net included in the package.
- Dicloplast should be applied only to intact, undamaged skin and not to injured skin or open wounds, and should not be kept on when bathing.
- Avoid contact of the Dicloplast with the eyes or mucosal tissues (e.g., nose and mouth), the genital and anal areas. If the patch comes into contact with these areas, wash the area well with water.
- Do not cut the patch.

If you forgot to apply this medicine at the required time, do not apply an additional patch. Apply the next patch at the regular time.

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

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

4. SIDE EFFECTS:

As with any medicine, the use of Dicloplast 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.

Some uncommon and very rare side effects might be serious.

If any of the following signs indicating allergy occur, stop using the medicine and consult with a doctor immediately:

- Swelling of the lips, eyes or tongue, wheezing or asthma attack, which are signs of severe allergic reaction (occur in less than 1 user out of 10,000).
- Rash, stinging or burning at the site where the patch was applied (occur in 1-10 users out of 1,000).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist):

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

- Itchy skin

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Skin rash
- Reddening of the skin
- Tiny red or purple spots under the skin

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Dry scaly skin
- Swelling at the site where the patch was applied

Additional very rare side effects – effects that occur in less than 1 user out of 10,000:

- Skin rash that worsens with exposure to the sun

Because Dicloplast is applied to the skin over the affected area, there is less risk of unwanted effects, such as stomach problems, e.g.:
pain, indigestion, or any signs of bleeding in the stomach or intestine, that can occur when diclofenac is taken by mouth. However, if used incorrectly, these unwanted effects could occur.

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 with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not use the medicine after the expiry date (EXP) that appears on the package. The expiry date refers to the last day of that month.
Do not store at a temperature exceeding 25°C.
Store in the original package.
The patches can be used within 3 months of opening the sachet.
After removing a patch from the sachet, close the sachet and make sure that it is sealed well.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
D-Sorbitol Solution (70%), Purified Water, 1,3 Butylene Glycol, Sodium Carboxyvinyl Polymer, Carboxymethylcellulose Sodium, Kaolin, Propylene Glycol, Gelatin (Type A), Povidone (K 90), Tartaric Acid, Titanium Oxide, Dihydroxyaluminium Aminoacetate, Polysorbate 80, Disodium Edetate, Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Fragrance, Polyester Unwoven Fabric, Polypropylene Film.

What does the medicine look like and what are the contents of the package:
The Dicloplast package contains 2 or 5 patches. The patch is approximately 10 x 14 cm in size, mildly fragranced and is made of a white-pale yellow non-woven fabric.

The package also contains an elastic, polyester, tubular net made of a non-woven fabric.

Not all package sizes may be marketed.

License holder/ importer and address: CTS Ltd., 4 Haharash St., Hod Hasharon 4524075.

Manufacturer and address: IBSA Institut Biochimique, Switzerland.

This leaflet was revised in 06/2021 according to Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 129-72-28525