PATIENT INFORMATION LEAFLET

VILONIT® GEL 1%
Diclofenac Diethylammonium

Please read this leaflet carefully before you start to take your medicine. It contains important information.

VILONIT® can be given without a prescription from your Physician. You should use VILONIT® carefully in order to have the best results.

- Keep this leaflet in a safe place. You may need to read it again.
- If you have any questions or if there is something you don't understand, please ask your doctor or pharmacist.
- You should contact your doctor if your symptoms get worse or do not get better after 14 days.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What VILONIT® is and what it is used for
2. What you should know before you use VILONIT®
3. How to use VILONIT®
4. Possible side effects
5. How to store VILONIT®
6. Other information

1. WHAT VILONIT® IS AND WHAT IT IS USED FOR

VILONIT® is formulated for topical administration only.
VILONIT® contains diclofenac, an active substance which belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
VILONIT® can relieve the symptoms of inflammation, such as swelling and pain, but it has no effect on the causes of the inflammation.

It is used, as potentially effective, for the local symptomatic relief of pain and inflammation in:

- trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises
- localised forms of soft tissue rheumatism (tenosynovitis, scalenus syndrome, thylacitis and periarthritis)
- For the treatment of osteoarthritis of superficial joints

It is recommended that the treatment should not be continued more than 14 days.

2. WHAT YOU SHOULD KNOW BEFORE YOU USE VILONIT®

Do not use VILONIT® **:**

If you have ever had allergy (hypersensitivity) to diclofenac, aspirin and other non-steroid anti-inflammatory drugs, propylene glycol, isopropanol or any of the other ingredients of VILONIT®, listed at the end of this leaflet.

If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing ; swelling of the face, lips, tongue or other parts of the body ; rash, itching or hives of the skin.

Special care should be taken with VILONIT® **GEL when :**

VILONIT® should not be applied to diseased skin, skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth or applied in the vagina.

In case VILONIT® comes into contact with the eyes, rinse your eyes with plenty of water and consult your doctor.

VILONIT® is for cutaneous use only. Do not use VOSTAR® GEL orally. The product should never be swallowed.

Taking other medicines

Tell you doctor if you are taking any other medicines, including any that you buy without a prescription.

Pregnancy and lactation

Do not use VILONIT® if you are pregnant or if you breast-feed your baby.

Ask for your doctor's advice before you take any medicine.

VILONIT® contains propylene glycol, which may cause mild, localised skin irritation in some people.

Driving and operating machines

None known.

However, when VILONIT® is applied to relatively large areas of skin over a prolonged period of time, the possibility of systemic side effects cannot be excluded. Therefore, patients feeling dizzy or having other disorders of the CNS, should not drive or operate machines.

3. HOW TO USE VOSTAR®

You should always use VILONIT® according to the instructions. If you are not sure about something, ask your doctor or pharmacist.

Adults

VILONIT® should be rubbed gently into the skin**.** Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3 - 4 times a daily. After application, the hands should be washed unless they are the site being treated. You should not continue the treatment after 2 weeks. If after a 7-day treatment your condition has not improved, consult your doctor.

If you forget to use it

If you forget to use VILONIT®, use it as soon as you remember and then go back to your normal schedule. Do not use a double dose to make up for the one that you missed.

If you swallow VILONIT® **by mistake, call your doctor immediately.**

4. POSSIBLE SIDE EFFECTS

All medicines can have side effects. Sometimes they are serious, most of the time they are not.
Undesirable effects include mild skin reactions at the site of application. In very rare cases, allergic reactions may appear.
Undesirable effects are ranked under heading of frequency :
Infections and infestations : Very rare : Rash postular
Immune system disorders : Very rare : Hypersensitivity, angioneurotic oedema
Respiratory, thoracic and mediastinal disorders : Very rare : Asthma
Skin and subcutaneous tissue disorders :
Common: Rash, eczema, erythema, dermatitis (including dermatitis contact)
Rare: Dermatitis bullous
Very rare: Photosensitivity reactions

If any of the following happen, **STOP taking this medicine and tell your doctor IMMEDIATELY**.
Extended skin rash.
Stridor, troubled breathing or swelling of the face.

If any of the symptoms become troublesome or if you notice anything else not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE VILONIT®

Keep the medicine out of reach and sight of children.
Do not use VOSTAR® after the expiry date which is printed on the outside of the pack.
Any unused medicine should be returned to your pharmacist.
Store below 30^0C. Protect from light and heat. You should not burn or make a hole at the tube even if it is empty.

Medicines should not be disposed in the sewage or in the garbage.
Ask your pharmacist how to dispose any unwanted medicines. These measures will help protect the environment.

6. OTHER INFORMATION

VILONIT® contains:
Active ingredient : Diclofenac diethylammonium 1.16%, equivalent to diclofenac sodium 1%
Other ingredients : Diethylamine, Carbomer 934 P, Cetomacrogol 1000, Cetiol LC, Isopropanol, Paraffin,liquid, Levanda flavor, Propylene glycol, Water purified.

VILONIT® is a white gel. It is supplied in tubes containing 100g gel and printed with the product's and manufacturer's characteristics. Each box contains one tube (100g) and a patient information leaflet.

Marketing Authorization Holder and Manufacturer
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