

DOSANAC EMULSION GEL®

Diclofenac Sodium (1g/100g)

What is in this leaflet

1. What DOSANAC EMULSION GEL® is used for
2. How DOSANAC EMULSION GEL® works
3. Before you use DOSANAC EMULSION GEL®
4. How to use DOSANAC EMULSION GEL®
5. While you are using it
6. Side effects
7. Storage and Disposal of DOSANAC EMULSION GEL®
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What DOSANAC EMULSION GEL® is used for

DOSANAC EMULSION GEL® is used for the relief of pain in:

-traumatic inflammation of the tendons, ligaments, muscles and joints.

-localized forms of soft-tissue rheumatism, e.g. tendinitis (inflammation of the tendon).

- localized painful joint disease.

How DOSANAC EMULSION GEL® works

DOSANAC EMULSION GEL® contains the active substance diclofenac which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and it is used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles.

Before you use DOSANAC EMULSION GEL®

-When you must not use it

Do not use DOSANAC EMULSION GEL® if you have:

- an allergy to any of the ingredients listed under the Ingredients section of this leaflet
- ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin, ibuprofen or other NSAIDs. Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath, skin rash or hives, swelling of the face or tongue or runny nose.

This medicine is not recommended for use in children.

Do not use DOSANAC EMULSION GEL® if:

- the expiry date (Exp.) on the carton has passed

Please consult your healthcare professional if you are unsure about any of the above.

-Before you start to use it

Please inform your healthcare professional if you have or have had any of the following conditions:

- Ulceration, bleeding and perforation of the stomach and intestines.

- Heart disease or stroke.
- Diclofenac gel may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin blisters and skin peeling. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Please consult your doctor before start to use DOSANAC EMULSION GEL® if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking DOSANAC EMULSION GEL® against the benefits they expect it will have for you.

-Taking other medicines

Tell your healthcare professional if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Do not use DOSANAC EMULSION GEL® if you are already taking diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin or ibuprofen).

A more complete list of medicines to be careful with or avoid while using DOSANAC EMULSION GEL® can be obtained from your healthcare professional.

DOSANAC EMULSION GEL®

Diclofenac Sodium (1g/100g)

How to use DOSANAC EMULSION GEL®

-How much to use

Apply 2-4g (3-8cm length) to the affected parts and gently massage the applied area to ensure that the gel is absorbed into the skin.

-When to use it

DOSANAC EMULSION GEL® should be applied 3-4 times daily to the affected parts.

-How long to use it

Do not use DOSANAC EMULSION GEL® for more than 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis.

If you are using the gel for arthritis, your doctor may wish to review your treatment regularly.

If symptoms do not improve within this time, or they get worse, consult your doctor.

-If you forget to use it

If you miss your application of DOSANAC EMULSION GEL® at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten application.

Check with your healthcare professional if you are unsure of what to do or if you miss more than one dose.

-If you use too much (overdose)

Immediately inform your doctor for advice if you suspect that you or anyone else may have applied too much or accidentally swallowed DOSANAC EMULSION GEL®.

Alternatively, go to your nearest hospital. Do this even if you are not experiencing signs of discomfort or poisoning as you may need urgent medical attention.

While you are using DOSANAC EMULSION GEL®

-Things you must do

Apply your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are applying DOSANAC EMULSION GEL®.

DOSANAC EMULSION GEL® should be applied only to intact, non-diseased skin.

-Things you must not do

Do not apply to skin wounds or open injuries.

Do not allow DOSANAC EMULSION GEL® to come into contact with your eyes or mucous membrane, and should never be taken by mouth.

-Things to be careful of

Do not apply the gel to skin that has

- a rash or eczema
- cuts or open wounds

Be careful when sunbathing or

exposing yourself to sunlight as your skin may be more sensitive to sunlight.

If you have a stomach or duodenal ulcer (or a history of), tell your healthcare professional before using the gel.

If you accidentally put DOSANAC EMULSION GEL® into your eyes, rinse your eyes well with clean water. Consult your healthcare professional if any discomfort persists.

Side effects

All medicines can have side effects which are occasionally serious.

Inform your healthcare professional if you notice any of the following:

- skin rash, itching, reddening or smarting (sharp, stinging pain) of the skin
- increased skin sensitivity to the sun (Possible signs are sunburn with itching, swelling and blistering.)

Inform your healthcare professional immediately and stop using DOSANAC EMULSION GEL® if you experience any of the following:

- skin rash with blisters, hives
- wheezing, shortness of breath or asthma/feeling of tightness in the chest
- swelling of the face, lips, tongue or throat that may cause difficulty in swallowing, breathing or speaking

DOSANAC EMULSION GEL[®]

Diclofenac Sodium (1g/100g)

This is not a complete list of all possible side effects. Please consult your healthcare professional for further information.

You may report any side effects or adverse drug reactions to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of DOSANAC EMULSION GEL[®]

-Storage

- Keep DOSANAC EMULSION GEL[®] away from children in a place where they cannot reach.
- Store below 25°C.
- Keep away from heat and light.

-Disposal

Consult your healthcare professional for disposal of DOSANAC EMULSION GEL[®] that have passed their expiry date or if you have been instructed to stop the medicine.

Product Description

-What it looks like

DOSANAC EMULSION GEL[®] is a white gel. Each tube contains 25g of gel.

-Ingredients

Active ingredient:

Diclofenac diethylammonium corresponding to 1g of diclofenac sodium in every 100g of DOSANAC EMULSION GEL[®].

Inactive ingredients:

Carboxy methyl cellulose, isopropyl alcohol, essential oil, triethanolamine, polysorbate 80, propylene glycol, carbomer 940 and isopropyl Alcohol.

-MAL number:

MAL19990579A

Manufacturer

Siam Bheasach Co., Ltd.,
123 Soi Chokechairuammitr,
Vibhavadi-Rangsit Road,
Chatuchak, Bangkok 10900 and
9 Soi Chokechairuammitr 3,
Vibhavadi-Rangsit Road,
Dindang, Bangkok 10400,
Thailand.

Product Registration Holder

SPG Pharma (Malaysia) Sdn.
Bhd.,
Suite 1701, Block A,
Damansara Intan e-Business
Park, No. 1, Jalan SS20/27,
47400 Petaling Jaya, Selangor
Darul Ehsan, Malaysia.

Date of revision

18/02/2016

Serial Number:

BPFK(R4/1)150216/00029