Package leaflet: Information for the patient

Motusol™ Max 2 % w/w Gel
diclofenac sodium
For adults and adolescents aged 14 years and over

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 - 5 days.

What is in this leaflet

1. What Motusol Max is and what it is used for

Motusol Max contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Motusol Max is indicated in adults and adolescents aged 14 years and over.

For adults and adolescents aged 14 years and over
For the local symptomatic treatment of pain in acutestrains, sprains or contusions following blunt trauma

For adolescents aged 14 years and over the medicine is intended for short term treatment.

2. What you need to know before you use Motusol Max

DO NOT use Motusol Max:
- if you are allergic to diclofenac or any of the other ingredients of this medicine listed in section 6.
- if you have ever developed breathing problems (asthma, bronchospasm), hives, runny nose, or swelling of the face or tongue after taking/using acetylsalicylic acid or another non-steroidal anti-inflammatory drugs (e.g. ibuprofen);
- on open injuries, inflammations or infections of the skin as well as on eczema or mucous membranes;
- in the last trimester of pregnancy “see Pregnancy”;
- in children and adolescents under 14 years of age;

Warnings and precautions
Talk to your doctor before using Motusol Max:
You are more likely to asthma attacks (so-called analgesic intolerance / analgesic asthma), local skin or mucous membrane swelling (so-called quincke oedema) or hives than other patients if you suffer from

asthma, hay fever, swelling of the nasal membrane (so-called nasal polyps) or chronic obstructive pulmonary disease, chronic respiratory tract infections (particularly associated with hay fever-like symptoms) or hypersensitivity to other painkillers and anti-rheumatic medicines of any kind.
In these patients, Motusol Max may only be used under certain precautions (emergency preparedness) and direct medical supervision. The same applies for patients who are also allergic to other substances e.g. with skin reactions, itching or hives.

When Motusol Max is applied to a large area of skin and over a prolonged period, the possibility of systemic side-effects from the application of Motusol Max cannot be excluded.

Apply Motusol Max only to intact, not diseased or injured skin. Avoid contact with eyes and oral mucous membranes. The gel must not be taken orally.

After applying the gel on the skin you can use a permeable (non-occlusive) bandage but allow the gel to dry on the skin for a few minutes. Do not use an airtight occlusive dressing.

If the symptoms worsen or do not improve after 3 - 5 days, consult a doctor.

The use of Motusol Max should be discontinued if you develop a skin rash.

Avoid sun exposure, including solarium, when using this medicine.
Precautions should be taken to prevent children from touching the area to which the gel is applied.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents
Motusol Max is contraindicated in children and adolescents under 14 years.

Other medicines and Motusol Max
Tell your doctor or pharmacist if you are taking, have recently taken or might take/use any other medicines.
In intended, cutaneous use of Motusol Max no interactions have become known so far.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy
Do not use Motusol Max during the last trimester of pregnancy as it could harm your unborn child or cause problems at delivery. During the first and second trimester of pregnancy, Motusol Max should be used only after consultation with your doctor.

Breast-feeding
Motusol Max should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. Do not apply Motusol Max on the breasts if you are a nursing mother nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines
Motusol Max has no or neligible influence on the ability to drive or to use machines.

Motusol Max contains Propylene glycol (E1520)
This medicine contains 54 mg propylene glycol in 1 g of gel.

Motusol Max contains Butylhydroxytoluene (E321)
Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Motusol Max contains fragrances
This medicine contains fragrance with benzyl alcohol (0.15 mg/g), citral, citronellol, coumarin, eugenol, farnesol, geraniol, d-limonene and linalool which may cause allergic reactions.
In addition, benzyl alcohol may cause mild local irritation.

3. How to use Motusol Max

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 14 years and over
Motusol Max is used 2 times a day (preferably morning and evening).

Depending on the size of the affected site to be treated, a cherry to walnut sized quantity, corresponding to 1 - 4 g of gel is required.

The maximum daily dose is 8 g of gel.

Elderly patients
No special dose adjustment is necessary. If you are elderly,you should pay special attention to side effects and, if necessary, consult a doctor or pharmacist.

Impaired kidney or liver function
No dose reduction is necessary.

Use in children and adolescents (under 14 years)
Motusol Max is contraindicated in children and adolescents under 14 years (see section 2 “Do not use Motusol Max”).

Before using for the first time, open as follows:
1. Unscrew the cap from the tube. To open the safety seal of the tube, reverse the cap and engage with the nozzle. Do not use scissors or other sharp objects!
2. Twist and remove the plastic seal from the tube. Use the gel as described in this leaflet. Do not use if the seal is broken.

How to apply:
Motusol Max is for cutaneous use.
Apply the gel to the affected parts of the body thinly and rub gently into the skin. Unless the hands are the site being treated, wash your hands after rubbing in the gel.

Duration of treatment:
The duration of use depends on the symptoms and the underlying disease Motusol Max should not be used longer than 1 week without medical advice.

If symptoms worsen or do not improve after 3 – 5 days a doctor should be consulted.

If you use more Motusol Max than you should

An overdose is unlikely to happen if you use more Motusol Max than you should, because the absorption into the blood stream is low when used on the skin. If the recommended dose is significantly exceeded when used on the skin, the gel should be removed and washed off with water.
If you accidentally swallow Motusol Max, contact your doctor who decides on the appropriate measures.

If you forget to use Motusol Max
Do not use a double dose to make up for a forgotten application.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some rare and very rare side effects may be serious.
If you experience any of the following signs of allergy, **stop** using Motusol Max and tell a doctor or pharmacist immediately:
- Skin rash with blisters; hives (may affect up to 1 in 1,000 people),
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). (may affect less than 1 in every 10,000 people).
- Swelling of the face, lips, tongue or throat. (may affect up 1 in 10,000 people).

Other side effects are possible:

Common side effects (may affect up to 1 in 10 people):
Skin rash, itching, reddening, eczema, dermatitis (inflammation of the skin) including contact dermatitis.

Uncommon side effects (may affect up to 1 in 100 people):
Scaling, dehydration of the skin, swelling (oedema)

Very rare side effects (may affect up 1 in 10,000 people)
Pustular rash, gastrointestinal complaints, hypersensitivity reactions (including hives), sensitivity to light with appearance of skin reactions after exposition to sunlight.

Not known side effects (cannot be estimated from the available data).
Burning sensation at the application site, dry skin

When Motusol Max is applied to a large area of skin and over a prolonged period, the possibility of systemic side-effects (e.g. renal, hepatic or gastrointestinal side effects, systemic hypersensitivity reactions) - as they occur possibly after systemic administration of diclofenac-containing medicines cannot be completely excluded.

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Motusol Max

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

Store in the original tube in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Please, do not apply the ointment shortly before taking a shower or bath. These measures will help protect the environment.

6. Contents of the pack and other information

What Motusol Max contains

- The active substance is diclofenac sodium.
- 1 g contains 23.2 mg diclofenac diethylamine corresponding to 20 mg diclofenac sodium.
- The other ingredients are isopropyl alcohol, propylene glycol (E1520), cocoyl caprylocaprate, liquid paraffin, carbomer, macrogol cetostearyl ether, diethylamine, oleic acid, butylhydroxytoluene, fragrance (containing citronellol, geraniol, benzyl alcohol, linalool, limonene, citral, farnesol, coumarin, eugenol), purified water.

What Motusol Max looks like and contents of the pack

Motusol Max is a white to almost white, homogeneous gel, packed in aluminium laminated tubes, closed with PE seal and PP screw caps, available in pack sizes: 30g, 50g, 60g, 100g, 150g, 180g per tube.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva B.V., Swensweg 5, 2031 GA Haarlem, Netherlands

Manufacturer
Merckle GmbH, Graf-Arco-Str.3, D-89079 Ulm, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: ratioDolor Diclofenac 2% Schmerzgel
Belgium: Kinespir Forte 20 mg/g gel
Czech Republic: DiclofenacTeva
Estonia: Olfen
Finland: Diclofenac ratiopharm 23,2 mg/g geeli
Germany: Diclofenac AbZ Schmerzgel
Hungary: Diclofenac Teva Forte 20mg/g gél
Croatia: Diklofenaknatrij Pliva 20 mg/g gel
Ireland: Motusol Max 2% w/w Gel
Iceland: Diclofenac Teva
Italy: DICLOFENAC TEVA BV
Latvia: Olfen 23,2 mg/g gels
Lithuania: Olfen 2,32% gelis
Luxembourg: Diclofenac AbZ Schmerzgel
Norway: Diclofenac diethylamine Teva
Portugal: OlfenEX Dor
Poland: Olfen MAX
Slovakia: Diklofenak- dietylamin Teva 23,2 mg/g gél

This leaflet was last revised in July 2021