

Motusol[®] MAX

12-Hour Pain Relief 2.32% w/w Gel

diclofenac diethylamine



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.

You should check with your doctor or pharmacist if you are not sure.

- This medicine is available without prescription. However, you still need to use Motusol MAX 12-Hour Pain Relief carefully to get the best results from it. Note that this leaflet is revised on a regular basis with the latest information on your medicine. Please refer to the date at the end of the leaflet.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your signs of illness worsen or do not improve after 7 days.
- If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your doctor or pharmacist.

What is in this leaflet

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2. What you need to know before you use Motusol MAX 12-Hour Pain Relief
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1. What Motusol MAX 12-Hour Pain Relief is and what it is used for

This medicine contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin.

Motusol MAX 12-Hour Pain Relief is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. This medicine can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function
- tendonitis (e.g. tennis elbow), swelling around elbow or knee.

Motusol MAX 12-Hour Pain Relief is intended for use in adults and children aged 14 years and older.

2. What you need to know before you use Motusol MAX 12-Hour Pain Relief

DO NOT use Motusol MAX 12-Hour Pain Relief if you:

- are allergic (hypersensitive) to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting), or any of the other ingredients of this medicine (see Section 6 and end of Section 2). If you are not sure, ask your doctor or pharmacist. Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma); skin rash with blisters or hives; swelling of the face or tongue; runny nose.
- have severe joint pain of recent onset that is not related to an injury or period of overuse
- feel ill, have a temperature or any other symptoms that accompany the pain
- are in the last 3 months of pregnancy.

If any of these apply to you, do not use this medicine.

Take special care with Motusol MAX 12-Hour Pain Relief

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- This medicine is only for use on your skin. Do not use it in the mouth. Do not swallow it. Wash your hands after use unless they are the area to be treated. Be careful not to get Motusol MAX 12-Hour Pain Relief in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.
- A brace or wrap commonly used for injuries like sprains can be used, but do not use the gel under airtight (plastic) bandages.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.
- 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.

If you have any questions, talk to your doctor or pharmacist before using Motusol MAX 12-Hour Pain Relief.

This medicine is not recommended for use in children under 14 years of age.

Taking other medicines with Motusol MAX 12-Hour Pain Relief

Please tell your doctor or pharmacist if you are taking, or have recently taken, or want to start taking any other medicines, including those obtained without a medical prescription.

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 12-Hour Pain Relief if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. You should not use Motusol MAX 12-Hour Pain Relief during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of Diclofenac can cause adverse effects in your unborn baby. It is not known if the same risk applies to Motusol MAX 12-Hour Pain Relief when it is used on the skin.

Breast-feeding

This medicine should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Motusol MAX 12-Hour Pain Relief should not be applied on the breasts of nursing mothers nor 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 breast-feeding.

Motusol MAX 12-Hour Pain Relief contains:

Propylene glycol (E1520)

Propylene glycol may cause skin irritation.

Butylhydroxytoluene (E321)

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

Fragrances

This medicine contains fragrance with benzyl alcohol (0.15 mg/g, E1519), 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 12-Hour Pain Relief

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

How much Motusol MAX 12-Hour Pain Relief to use

Adults and adolescents 14 years and over

Apply the gel 2 times a day (preferably morning and evening) on the painful area.

How to apply:

1. To remove the seal before first use, unscrew the cap from 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. Do not use if the seal is broken.
3. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. The amount needed will vary depending upon the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient (2-4 g). You may notice a slight cooling effect when you rub the gel in. Only use the smallest amount of this medicine needed to relieve your pain, but never use more than 8 g per day and 56 g in one week.
4. Unless the hands are the site being treated, wash your hands after rubbing in the gel, to avoid accidental contact with the mouth and eyes (see Section 2).

This gel is for use only on the skin.

How long to use Motusol MAX 12-Hour Pain Relief for

Do not use this medicine for more than 14 days unless longer treatment is recommended by a doctor.

If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor. In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

If you use more Motusol MAX 12-Hour Pain Relief than you should

- If you use more gel than you should, wipe off the surplus gel with a tissue.
- If you or a child accidentally swallows the gel, contact your doctor immediately.

If you forget to use Motusol MAX 12-Hour Pain Relief

If you miss your application of this medicine at the correct time, apply it when you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten application. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Motusol MAX 12-Hour Pain Relief can cause side effects, although not everybody gets them.

Some rare and very rare side effects might be serious

If you experience any of the following signs of allergy, STOP using this medicine and tell a doctor or pharmacist immediately:

- Skin rash with blisters; hives. (These side effects are likely to affect 1 to 10 people in every 10,000).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma). (These

side effects are likely to affect less than 1 person in every 10,000).

- Swelling of the face, lips, tongue or throat. (These side effects are likely to affect less than 1 person in every 10,000).

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

Common: may affect up to 1 in 10 people in every 100 people

- skin rash, itching, reddening or smarting of the skin, dermatitis (including contact dermatitis).

Uncommon side effects (may affect up to 1 in 100 people in every 1000 people):

- scaling, dehydration of the skin, swelling (oedema).

Very rare: may affect less than 1 in 10,000 people

- the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

Not known: frequency cannot be estimated from the available data

- local application site irritation, peeling of the skin and discolouration, burning sensation at the application site, dry skin.

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 Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Motusol MAX 12-Hour Pain Relief

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.

This medicinal product does not require any special temperature storage conditions.

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 12-Hour Pain Relief contains

- The active substance is diclofenac.
- 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 (E570), butylhydroxytoluene (E321), fragrance (containing citronellol, geraniol, benzyl alcohol (E1519), linalool, limonene, citral, farnesol, coumarin, eugenol), purified water.

What Motusol MAX 12-Hour Pain Relief looks like and contents of the pack

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 per tube.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

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

This leaflet was last revised in September 2024.

PL 00289/2538

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