**Package leaflet: Information for the patient**

Motusol Rx 1 % w/w Gel
diclofenac (as diclofenac diethylamine)

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 Rx 1 % w/w Gel is and what it is used for

Motusol Rx 1 % w/w Gel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Motusol Rx 1 % w/w Gel is indicated in adults and adolescents aged 14 years and over.

**For adults**
For the symptomatic treatment of pain:
- in acute strains, sprains or contusions following blunt traumas
- of the soft tissues close to the joint (e.g. bursae, tendons, tendon sheaths, ligaments, muscle insertions and joint capsules) in osteoarthritis of knee and finger joints
- in epicondylitis (inflammation of the tendon insertions in the area of the elbow, also called tennis elbow or golfer elbow)
- in acute muscular pain, e.g in the back area.

**For adolescents aged 14 years and over**
For short-term treatment.
For local, symptomatic treatment of pain in acute strains, sprains or contusions following blunt trauma.

## 2. What you need to know before you use Motusol Rx 1 % w/w Gel

**Do not use Motusol Rx 1 % w/w Gel**
- 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), skin reactions (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
- if you are in the last 3 months of pregnancy (see “Pregnancy”)

- in children and adolescents under 14 years of age.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Motusol Rx 1 % w/w Gel.

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 Rx 1 % w/w Gel 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 Rx 1 % w/w Gel is applied to a large area of skin and over a prolonged period, the possibility of systemic side-effects from the application of Motusol Rx 1 % w/w Gel cannot be excluded. These side effects are similar to those that may occur when taking other medicines containing diclofenac. The gel should therefore be used with caution by patients with reduced kidney function, reduced heart function or reduced liver function as well as patients with active peptic ulcers in the stomach or duodenum.

Apply Motusol Rx 1 % w/w Gel only to intact, not diseased or injured skin. Avoid contact with eyes and 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 with an airtight occlusive dressing.

In acute conditions that are associated with severe redness, swelling, or overheating of joints, in prolonged joint pain or severe back pain that radiates into the legs and / or is associated with neurological deficiencies (e.g. numbness, tingling)a doctor should be consulted.

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

The use of Motusol Rx 1 % w/w Gel should be discontinued if you develop a skin rash.

During treatment photosensitivity can occur with the appearance of skin reactions after exposition to sunlight.

Precautions should be taken to prevent children from touching the area to which the gel is applied.

**Children and adolescents**
Motusol Rx 1 % w/w Gel is contraindicated in children and adolescents under 14 years.

**Other medicines and Motusol Rx 1 % w/w Gel**
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.
In intended, cutaneous use of Motusol Rx 1 % w/w Gel 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 Rx 1 % w/w Gel during the last trimester of pregnancy as it could harm your unborn child or cause problems at delivery. You should not use Motusol Rx 1 % w/w 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 Rx 1 % w/w Gel when it is used on the skin.

**Breast-feeding**
Use Motusol Rx 1 % w/w Gel only under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. Do not apply Motusol Rx 1 % w/w Gel 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 Rx 1 % w/w Gel has no or negligible influence on the ability to drive or to use machines.

**Motusol Rx 1 % w/w Gel contains Propylene glycol (E1520)**
This medicine contains 50 mg propylene glycol in 1 g of gel.
**Motusol Rx 1 % w/w Gel contains fragrances**
This medicine contains fragrance with benzyl alcohol (0.15 mg/g gel), 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 Rx 1 % w/w Gel

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 Rx 1 % w/w Gel is used 3 - 4 times a day.

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

The maximum daily dose is 16 g of gel.

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

**Elderly**
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)**
There are insufficient data on efficacy and safety in children and adolescents under 14 years of age (see section 2 “Do not use Motusol Rx 1 % w/w Gel”).

**Use in adolescents (14 years and over)**
In adolescents aged 14 years or over, if this medicine is needed 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.
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**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 Rx 1 % w/w Gel is for cutaneous use only.
The gel is applied to the affected parts of the body thinly and gently rubbed into the skin. Afterwards, the hands should be wiped with a paper towel and then washed, unless the hands are the area to be treated.

If too much gel is accidently applied, the excess gel should be wiped with a paper towel.
The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.

Before applying a bandage, the gel should be left to dry for a few minutes on the skin.

**Duration of treatment**
The duration of use depends on the symptoms and the underlying disease. Motusol Rx 1 % w/w Gel should not be used longer than 1 week without medical advice.

**If you use more Motusol Rx 1 % w/w Gel than you should**
An overdose is unlikely to happen if you use more Motusol Rx 1 % w/w Gel than you should, because the absorption into the blood stream is low when used on the skin.
If you accidentally swallow Motusol Rx 1 % w/w Gel, contact your doctor who decides on the appropriate measures.

**If you forget to use Motusol Rx 1 % w/w Gel**
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 Rx 1 % w/w Gel 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 up to 1 in 10,000 people).
- Swelling of the face, lips, tongue or throat (may affect up to 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** (frequency cannot be estimated from the available data)
Burning sensation at the application site, dry skin.

When Motusol Rx 1 % w/w Gel 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 Rx 1 % w/w Gel

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 after EXP. 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. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Motusol Rx 1 % w/w Gel contains**

- The active substance is diclofenac.

1 g contains 11.6 mg diclofenac diethylamine corresponding to 10 mg diclofenac sodium.

- The other ingredients are carbomer, cocoyl caprylocaprate, macrogol cetostearyl ether, liquid paraffin, diethylamine, isopropyl alcohol, propylene glycol (E1520), fragrance (containing benzyl alcohol, citral, citronellol, coumarin, eugenol, farnesol, geraniol, d-limonene and linalool), purified water.

**What Motusol Rx 1 % w/w Gel looks like and contents of the pack**

Motusol Rx 1 % w/w Gel 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: 30 g, 50 g, 60 g, 100 g, 120 g, 150 g per tube.

Not all pack sizes may be marketed.

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

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

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Austria: ratioDolor Diclofenac Schmerzgel 1% Gel
Belgium: Kinespir 10 mg/g gel
Czech Republic: Diclofenac Teva
Finland: Diclofenac ratiopharm 11,6 mg/g geeli
Germany: Diclofenac AbZ Schmerzgel
Hungary: Diclofenac Teva 10mg/g gél
Croatia: Diklofenaknatrij Pliva 10 mg/g gel
Ireland: Motusol Rx 1 % w/w Gel
Iceland: Diclofenac Teva
Italy: DICLOFENAC TEVA BV
Luxembourg: Diclofenac AbZ Schmerzgel
Norway: Diclofenac diethylamine Teva
Portugal: Olfen Dor
Poland: Diclofenac diethylamine Teva
Slovakia: Diklofenak- diethylamín Teva 11,6 mg/g gél

**This leaflet was last revised in September 2025.**