

PATIENT LEAFLET: Information for the user

Flector Tissugel® 140 mg medicated plaster Diclofenac sodium (as diclofenac epolamine)

Read all of this leaflet carefully before start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What Flector Tissugel is and what it is used for
2. What you need to know before you use Flector Tissugel
3. How to use Flector Tissugel
4. Possible side effects
5. How to store Flector Tissugel
6. Contents of the pack and other information.

1. WHAT FLECTOR TISSUGEL IS AND WHAT IT IS USED FOR

Flector Tissugel belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Flector Tissugel is used to relieve the pain and inflammation of tennis elbow, golfer's elbow and a sprained ankle.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLECTOR TISSUGEL

Do not use Flector Tissugel:

- if you are allergic to diclofenac, acetylsalicylic acid (aspirin) or any other NSAID
- if you are allergic to any of the other ingredients of Flector Tissugel (listed in section 6)
- if you have asthma, breathing problems, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs
- if you are entering or are already beyond your 6th month of pregnancy
- if you currently have a stomach ulcer (peptic ulcer)
- if you have any damaged skin including weeping or infected areas, eczema, burns or wounds
- if you are a children or adolescent aged less than 16 years.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Flector Tissugel if:

- You have heart disease
- You have kidney disease
- You have liver disease
- You have had stomach ulcers in the past
- You have inflammatory bowel disease such as Crohn's disease or ulcerative colitis or you are susceptible to bleeding from your bowel
- You have asthma

- You have breathing problems, skin rash or a runny nose after taking acetylsalicylic acid (aspirin) or other NSAIDs
- You are taking diclofenac or other NSAIDs, as an oral or topical preparation
- You regularly use a sun-bed or sunbathe
- You are elderly as you may be more prone to side effects.

Children and adolescents

Do not use in case of children or adolescent aged less than 16 years

Other medicines and Flector Tissugel

If Flector Tissugel is correctly used the risk of interaction with other medicinal products is very low. However inform your doctor or pharmacist if recently you used or took or you are currently using or taking any other medicines.

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 taking this medicine.

Flector Tissugel must not be used if you are entering or are already beyond your 6th month of pregnancy, as it could harm your unborn child or cause problems at delivery. Flector Tissugel should only be used under medical advice before the 6th month of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Flector Tissugel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Flector Tissugel 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 breastfeeding.

Driving and using machines

Diclofenac medicated plaster application has no influence on the ability to drive and use machines.

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This medicine contains:

- propylene glycol which may cause skin irritation.
- methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and Dalin PH perfum containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptine carbonate, which may cause allergic reactions (possibly delayed).

3. HOW TO USE FLECTOR TISSUGEL

Always use Flector Tissugel exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults or adolescents 16 years of age and over

How many plasters to use

- **Tennis elbow or golfer's elbow**
 - Apply one plaster in the morning
 - Remove the plaster in the evening and apply a new one
 - Remove the plaster in the morning

Repeat these steps for a maximum of 14 days.

- **Ankle sprains**
 - Apply one plaster per day
 - Remove the plaster the next day and apply a new oneRepeat these steps for a maximum of 3 days.

Remember: Ankle sprains will normally improve within 3 days and elbow pain within 14 days. If they do not, or if your symptoms get worse, tell your doctor.

Use in children and adolescents (under 16 years of age)

There are insufficient data on efficacy and safety available for children and adolescents below 16 years (see Do not use Flector Tissugel).

In children aged 16 years and over, if the symptoms worsen, the patient/parents of the adolescent is/are advised to consult a doctor.

How to apply Flector Tissugel

- Cut the top off the resealable sachet, take out a plaster and carefully close the seal.
- Record the date on which the sachet was opened in the space provided
- Remove the plastic backing protecting the sticky side of the plaster.
- Apply the plaster to the skin around the painful or swollen area. If necessary, it may be held in place with an open weave gauze bandage or thin strips of tape. These can be obtained from your pharmacist.
- Do not cover the plaster with any other kind of dressing.
- The medicated plaster should be applied only to intact, non-diseased skin, and not to skin wounds or open injuries, and should not be worn when bathing or showering.
- Take care to keep the gel away from your eyes, nose, mouth, genital and anal areas. If gel does come into contact with these, rinse away with water.
- The plaster should not be cut.

If you forget to use Flector Tissugel

Do not apply an additional plaster to make up for a missed dose. Simply apply your next plaster as planned.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Flector Tissugel can cause side effects, although not everybody gets them.

Some uncommon and very rare side effects might be serious

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

- **Swelling of the lips, eyes or tongue, wheezing or asthma attack** which are signs of severe allergic reaction (affect less than 1 user in 10,000),
- **Rash, stinging or burning** at the site where the plaster was applied (affect 1 to 10 users in 1,000).

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

Common side effects (affect 1 to 10 users in 100)

- Itchy skin

Uncommon side effects (affect 1 to 10 users in 1,000)

- Skin rash
- Redness of the skin
- Tiny red or purple coloured spots under the skin

Rare side effects (affect 1 to 10 users in 10,000)

- Dry scaly skin
- Swelling at the site where the plaster was applied.

Very rare side effects (affect less than 1 user in 10,000)

- Skin rashes made worse by sunlight

Because Flector Tissugel is applied to the skin over the affected area, there is less risk of unwanted effects, such as stomach problems including pain, indigestion, or any signs of bleeding in the stomach or intestine, that can occur when diclofenac is taken by mouth. However, if Flector Tissugel is not used correctly, these unwanted effects could occur.

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 HPRRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLECTOR TISSUGEL

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 sachet and carton. The expiry date refers to the last day of that month.

Do not store above 25°C

Use within 3 months of opening the sachet. After removing each plaster, ensure the sachet is resealed.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flector Tissugel contains

The active substance is diclofenac epolamine. Each medicated plaster contains a total of 180 mg of diclofenac epolamine, corresponding to 140 mg diclofenac sodium (1% w/w).

The other ingredients are gelatine, povidone (K90), sorbitol, kaolin, titanium dioxide (E171), propylene glycol, methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), disodium edetate (E385), tartaric acid, aluminium glycinate, carmellose sodium, sodium polyacrylate, 1,3-butylene glycol, polysorbate 80, fragrance (containing containing amyl cinnamal, amylcinnamyl alcohol, benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamal, cinnamyl alcohol, citronellol, d-Limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronellal, isoeugenol, linalool, methyl heptene carbonate), purified water and unwoven polyester support.

For excipients with known effect see section 2.

What Flector Tissugel looks like and contents of the pack

Each medicated plaster consists of a white to pale yellow paste impregnated into a dressing with a removable clear plastic backing protecting an adhesive layer. Resealable sachets contain either 2 or 5 plasters.

Flector Tissugel comes in packs of 2, 5, 10 and 14 plasters per box. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing authorization holder

IBSA Farmaceutici Italia srl,
Via Martiri di Cefalonia 2
26900 Lodi, Italy

Manufacturer

Altergon Italia srl
Zona Industriale
83040 Morra De Sanctis (AV)
Italy

Distributed in Ireland by

Windzor Pharmaceutical Limited
The Crescent, Block B, Northwood Business Park,
Santry, Dublin 9

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