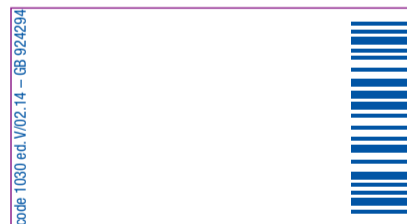


| | |
|----------------------------------------------------------------|--------------------------------------------|
| Order - AWF | AWF 19458 - OTDC 328388 |
| Reference | VOLT GEL PATCH 0010 GB_924294Z_PIL |
| Format | 195 x 220 mm - Recto/Verso |
| Pharma code | 10305 |
| Colour | P Reflex Blue U |
| Font | Helvetica Neue LT Pro |
| Minimum font size | 7 pt (all), 9 pt (body text) |
| Reference MKT | |
| Production site | IBSA - CH |
| Reference SITE | code 1030 ed. V/02.14 |
| Pre-press | Sonoco-Trident - 544874/2/DIS - 17/03/2014 |
| WARNING: Wrong display / print > switch overprint ON | |

RECTO



PATIENT LEAFLET: Information for the user

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 sections 4.

What is in this leaflet:

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

1. WHAT Voltarol Gel Patch is and what it is used for

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

Voltarol Gel Patch 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 Voltarol Gel Patch

Do not use Voltarol Gel Patch:

- if you are allergic to diclofenac, acetylsalicylic acid (aspirin) or any other NSAID
- if you are allergic to any of the other ingredients of Voltarol Gel Patch (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 Voltarol Gel Patch 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 old

Other medicines and Voltarol Gel Patch

If Voltarol Gel Patch 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.

Voltarol Gel Patch 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. Voltarol Gel Patch 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.

Voltarol Gel Patch should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Voltarol Gel Patch 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.

Voltarol Gel Patch contains

- preservatives known as parahydroxybenzoates which may cause allergic reactions (possibly delayed)
- and propylene glycol, which may cause skin irritation.

3. HOW TO USE Voltarol Gel Patch

Always use Voltarol Gel Patch 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

| | |
|-------------------|--------------------------------------------|
| Order - AWF | AWF 19458 - OTDC 328388 |
| Reference | VOLT GEL PATCH 0010 GB_924294Z_PIL |
| Format | 195 x 220 mm - Recto/Verso |
| Pharma code | 10305 |
| Colour | P Reflex Blue U |
| Font | Helvetica Neue LT Pro |
| Minimum font size | 7 pt (all), 9 pt (body text) |
| Reference MKT | |
| Production site | IBSA - CH |
| Reference SITE | code 1030 ed. V/02.14 |
| Pre-press | Sonoco-Trident - 544874/2/DIS - 17/03/2014 |

WARNING: Wrong display / print > switch overprint ON

VERSO

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 one
 - Repeat 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 Voltarol Gel Patch).

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 Voltarol Gel Patch

- 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 Voltarol Gel Patch

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 Voltarol Gel Patch 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 Voltarol Gel Patch 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 Voltarol Gel Patch 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 Voltarol Gel Patch 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 the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy. By reporting side effects you can help provide more information on the safety of this medicine.

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

5. HOW TO STORE Voltarol Gel Patch

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

Do not use after 3 months after the first 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 Voltarol Gel Patch 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 (propylene glycol, benzyle salicylate, phenyl ethyl alcohol, alpha amyl cinnamic aldehyde, hydroxycitronellal, phenylethyl phenylacetate, cinnamyl acetate, benzyl acetate, terpineol, cinnamic alcohol, cyclamenaldehyde.), purified water and unwoven polyester support.

What Voltarol Gel Patch 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.

Voltarol Gel Patch 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
Novartis Consumer Health, Camberley, GU15 3YL,

Manufacturers
Laboratoires Génévrier,
280 rue de Goa
Z.I. Les Trois Moulins, Parc de Sophia Antipolis
06600 Antibes, France

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

If this leaflet is difficult to see or read or you would like it in a different format, please contact Novartis Consumer Health, Camberley, GU15 3YL United Kingdom.

This leaflet was last revised in January 2014.

GB 924294
code 1030 ed. V/02.14



Approvals

Version:

| Name | 521 | Type | Reason for Signature | Date |
|------|-----|------|----------------------|------|
| | | | | |

Document electronically signed