

applied to the skin. Side effects can include dryness, itching, peeling, or scaling of treated

Starting at 30 weeks gestation, Flector Patch and other NSAIDs should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur. It is not known whether this drug is excreted in human milk.

skin. Other side effects can also occur.

Our Flector patch Side Effects Drug Center provides a comprehensive view of available drug information on the potential side effects when taking this medication.

- Side Effects & Drug Interactions
- Warnings & Precautions
- Overdosage & Contraindications
- Clinical Pharmacology
- Medication Guide

For Patients

- Flector Patch Overview
- Flector Patch in Detail with Side Effects

Pain Management Resources

- Top Tips for Pain Relief
- How to Save Money on Health Care
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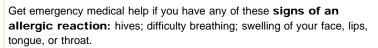
Ultram

Vicoprofen

Pain FAQs

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Flector Patch in Detail - Patient Information: Side Effects



Although the risk of serious side effects is low when diclofenac is applied to the skin, you should be aware of side effects that can occur if the medication is absorbed into your bloodstream.

Stop using this medicine and call your doctor at once if you have a serious side effect such as:

- chest pain, slurred speech, problems with vision or balance, and feeling weak or short of breath:
- bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds;
- pale or yellowed skin, dark colored urine, confusion;
- swelling or rapid weight gain, urinating less than usual or not at all;
- nausea, upper stomach pain, itching, loss of appetite, dark urine, claycolored stools, jaundice (yellowing of the skin or eyes);
- bruising, severe tingling, numbness, pain, muscle weakness;
- fever, sore throat, and headache with a severe blistering, peeling, and red skin rash; or
- the first sign of any skin rash, no matter how mild.

Less serious side effects may include:

- mild nausea, stomach pain, upset stomach;
- diarrhea, gas; or
- mild itching, dryness, redness, scaling, or other skin irritation where the medicine was applied.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Read the entire detailed patient monograph for Flector Patch (Diclofenac Epolamine Topical Patch) »

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Flector Patch Overview - Patient Information: Side Effects

SIDE EFFECTS: See also Warning section.

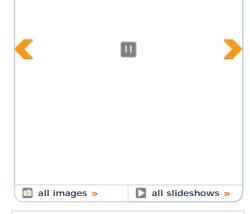
Itching, burning, irritation, redness, or dry skin may occur at the application site. Nausea or change in taste may also occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: swelling of the ankles/feet/hands (edema), sudden/unexplained weight gain, unusual tiredness, change in the amount of urine.

This drug may rarely cause serious (possibly fatal) liver problems. Get medical help right away if you have any symptoms of liver damage, including: dark urine, persistent nausea/vomiting/loss of appetite, stomach/abdominal pain, yellowing eyes/skin.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.



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Flector Patch

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"Nov. 2, 2012 -- Safety steps taken in the wake of the fungal meningitis outbreak have worsened drug shortages, raising questions about whether the U.S. must choose between the safety and the availability of crucial medicines.

Ameridos"...

(1)

Read the More Drug Shortages in Fungal Meningitis Aftermath article »





This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

Read the entire patient information overview for Flector Patch (Diclofenac Epolamine Topical Patch)»

Flector Patch FDA Prescribing Information: Side Effects (Adverse Reactions)

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SIDE EFFECTS

Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In controlled trials during the premarketing development of Flector Patch (diclofenac epolamine topical patch), approximately 600 patients with minor sprains, strains, and contusions have been treated with Flector Patch (diclofenac epolamine topical patch) for up to two weeks.

Adverse Events Leading to Discontinuation of Treatment

In the controlled trials, 3% of patients in both the Flector Patch (diclofenac epolamine topical patch) and placebo patch groups discontinued treatment due to an adverse event. The most common adverse events leading to discontinuation were application site reactions, occurring in 2% of both the Flector Patch (diclofenac epolamine topical patch) and placebo patch groups. Application site reactions leading to dropout included pruritus, dermatitis, and burning.

Common Adverse Events

Localized Reactions

Overall, the most common adverse events associated with Flector Patch (diclofenac epolamine topical patch) treatment were skin reactions at the site of treatment.

Table 1 lists all adverse events, regardless of causality, occurring in ≥ 1% of patients in controlled trials of Flector Patch (diclofenac epolamine topical patch) . A majority of patients treated with Flector Patch (diclofenac epolamine topical patch) had adverse events with a maximum intensity of "mild" or "moderate."

Table 1. Common Adverse Events (by body system and preferred term) in ≥ 1% of Patients treated with Flector Patch (diclofenac epolamine topical patch) or Placebo Patch ¹

	DICLOFENAC N=572		PLACEBO N=564	
	N	PERCENT	N	PERCENT
Application Site Conditions	64	11	70	12
Pruritus	31	5	44	8
Dermatitis	9	2	3	< 1
Burning	2	< 1	8	1
Other ²	22	4	15	3
Gastrointestinal Disorders	49	9	33	6

Nausea	17	3	11	2
Dysgeusia	10	2	3	< 1
Dyspepsia	7	1	8	1
Other3	15	3	11	2
Nervous System Disorders	13	2	18	3
Headache	7	1	10	2
Paresthesia	6	1	8	1
Somnolence	4	1	6	1
Other ⁴	4	1	3	< 1

¹ The table lists adverse events occurring in placebo-treated patients because the placebo-patch was comprised of the same ingredients as Flector Patch (diclofenac epolamine topical patch) except for diclofenac. Adverse events in the placebo group may therefore reflect effects of the non-active ingredients.

Foreign labeling describes that dermal allergic reactions may occur with Flector Patch treatment. Additionally, the treated area may become irritated or develop itching, erythema, edema, vesicles, or abnormal sensation.

Read the entire FDA prescribing information for Flector Patch (Diclofenac Epolamine Topical Patch) »

Related Resources for Flector Patch

Related Drugs

- Daypro
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- Ultracet
- Lodine
- Ultram
- Naprelan
- Vicoprofen
- Synera

Read the Flector Patch User Reviews »

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Next: Drug Description

Additional Flector Patch Information

- Flector Patch Side Effects Center
- Flector Patch in detail including Side Effects and Drug Images
- Flector Patch Overview including Precautions
- Flector Patch FDA Approved Prescribing Information including Dosage

Flector Patch - User Reviews



Flector Patch User Reviews

Now you can gain knowledge and insight about a drug treatment with Patient Discussions.

Here is a collection of user reviews for the medication Flector

² Includes: application site dryness, irritation, erythema, atrophy, discoloration, hyperhidriosis, and vesicles.

³ Includes: gastritis, vomiting, diarrhea, constipation, upper abdominal pain, and dry mouth.

 $^{^{4}}$ Includes: hypoaesthesia, $\ensuremath{\text{dizziness}}\xspace$, and hyperkinesias.

