

## **Package leaflet: Information for the patient**

### **Rivoltan<sup>®</sup> Devil's Claw 480 mg, Film-Coated Tablets**

For adults

Active substance: dry extract of devil's claw root

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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.

### **What is in this leaflet**

1. What Rivoltan<sup>®</sup> Devils Claw 480 mg is and what it is used for
2. What you need to know before you take Rivoltan<sup>®</sup> Devil's Claw 480 mg
3. How to take Rivoltan<sup>®</sup> Devil's Claw 480 mg
4. Possible side effects
5. How to store Rivoltan<sup>®</sup> Devil's Claw 480 mg
6. Contents of the pack and other information

#### **1. What Rivoltan<sup>®</sup> Devils Claw 480 mg is and what it is used for**

Rivoltan<sup>®</sup> Devil's Claw 480 mg is a herbal medicine for disorders affecting the musculoskeletal system.

Rivoltan<sup>®</sup> Devil's Claw 480 mg is used for the supportive treatment of musculoskeletal "wear and tear".

NB:

In case of an acute condition, for example associated with reddened, swollen or hot joints, or persisting complaints, a doctor must be consulted.

#### **2. What you need to know before you take Rivoltan<sup>®</sup> Devil's Claw 480 mg**

**Do not take Rivoltan<sup>®</sup> Devil's Claw 480 mg:**

- if you are allergic to devil's claw or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from stomach or duodenal ulcers.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Rivoltan<sup>®</sup> Devil's Claw 480 mg.

If you suffer from gallstones, you must consult a doctor.

## **Children and adolescents**

No adequate studies are available on the use of this medicine in children and adolescents. It should therefore not be used in children and adolescents under 18 years of age.

## **Other medicines and Rivoltan<sup>®</sup> Devil's Claw 480 mg**

No interactions are known.

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

## **Rivoltan<sup>®</sup> Devil's Claw 480 mg with food, drink and alcohol**

No special precautions need to be taken.

## **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.

No sufficient experience with pregnant and breast-feeding women is available yet. For that reason, Rivoltan<sup>®</sup> Devil's Claw 480 mg should not be used during pregnancy and breast-feeding.

## **Driving and using machines**

No special precautions need to be taken.

## **Rivoltan<sup>®</sup> Devil's Claw 480 mg contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Rivoltan<sup>®</sup> Devil's Claw 480 mg**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Unless prescribed otherwise, adults take 1 film-coated tablet twice daily.

Method of administration:

Oral use.

Rivoltan<sup>®</sup> Devil's Claw 480 mg Film-Coated Tablets should be taken with plenty of liquid (preferably a glass of water), without chewing, in the morning and evening after meals.

Do not take the film-coated tablets while lying down.

Duration of use:

There is no restriction for the duration of use. However, please in any case take note of the information provided in "1. What Rivoltan<sup>®</sup> Devils Claw 480 mg is and what it is used for" and "4. Possible side effects".

Talk to your doctor or pharmacist if you think that the effect of Rivoltan<sup>®</sup> Devil's Claw 480 mg is too strong or too weak.

**If you take more Rivoltan<sup>®</sup> Devil's Claw 480 mg than you should**

If you take the double or triple of the recommended individual dose (equivalent to 2-3 film-coated tablets of this medicine) by mistake once, this usually does not result in any negative effects. If you have taken significantly more than this, please contact your doctor. The doctor can then decide which measures are to be taken, if any. The side effects listed below may occur in enhanced form.

**If you forget to take Rivoltan<sup>®</sup> Devil's Claw 480 mg**

Do not take the double dose, but rather continue taking the medicine as described in this leaflet or as prescribed by your doctor.

**If you stop taking Rivoltan<sup>®</sup> Devil's Claw 480 mg**

Interrupting or stopping treatment early is usually safe. If in doubt, please ask your treating doctor.

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.

The following list covers all the known side effects from treatment with products containing devil's claw root, including those from higher doses and long-term treatment.

The stated frequencies of the side effects are based on the following categories:

Very common: may affect more than 1 in 10 treated  
Common: may affect 1 to 10 in 100 treated  
Uncommon: may affect 1 to 10 in 1,000 treated  
Rare: may affect 1 to 10 in 10,000 treated  
Very rare: may affect less than 1 in 10,000 treated  
Not known: cannot be estimated from the available data

**Possible side effects:**

Nervous system disorders:

*Rare:* dizziness, headache.

Gastrointestinal disorders:

*Rare:* diarrhoea, nausea, vomiting.

Metabolism and nutrition disorders:

*Very rare:* an increase in blood sugar levels, which resolved after discontinuing the medicine, was observed in insulin-dependent diabetes mellitus patients.

Immune system disorders:

*Very rare:* hypersensitivity reactions (skin rashes, hives, facial oedemas) to the point of circulatory collapse (anaphylactic shock).

**Countermeasures for side effects:**

If you experience any of the side effects listed above, in particular hypersensitivity reactions, please stop taking Rivoltan<sup>®</sup> Devil's Claw 480 mg and immediately consult a doctor so that they can determine the severity and decide about the measures to be taken, if any.

Rivoltan<sup>®</sup> Devil's Claw 480 mg must not be taken again if there are any signs of a hypersensitivity reaction.

**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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Rivoltan<sup>®</sup> Devil's Claw 480 mg**

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 blister pack after "EXP:". The expiry date refers to the last day of that month.

**Storage conditions:**

Do not store above 30°C.

**6. Contents of the pack and other information****What Rivoltan® Devil's Claw 480 mg contains**

The active substance is dry extract of devil's claw root LI 174

One film-coated tablet contains 480 mg dry extract of devil's claw root (4.4-5:1).  
Extracting agent: ethanol 60 % (V/V).

The other ingredients are:

maize starch, microcrystalline cellulose, lactose monohydrate, colloidal silica,  
magnesium stearate, hypromellose, macrogol 6000, talc, titanium dioxide (E 171).

*Advice for diabetics:*

One film-coated tablet is equivalent to 0.02 bread units.

**What Rivoltan® Devil's Claw 480 mg looks like and contents of the pack:**

Rivoltan® Devil's Claw 480 mg Film-coated tablets are oval, white, curved film-coated tablets.

Rivoltan® Devil's Claw 480 mg is available in packs of 20 film-coated tablets (N1),  
50 film-coated tablets (N2) and 100 film-coated tablets (N3).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Krewel Meuselbach GmbH  
Krewelstr. 2  
53783 Eitorf  
tel: +49 (0)2243 / 87-0  
fax: +49 (0)2243 / 87-175  
e-mail: info@krewelmeuselbach.de

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