

#### **MHRA**

151 Buckingham Palace Road London SW1W 9SZ United Kingdom

mhra.gov.uk

July 4, 2013

**Diclofenac: information for patients** 

### Summary and key messages

- Diclofenac is one of a group of important medicines (anti-inflammatory medicines) used to treat arthritis, and other conditions that cause pain and inflammation.
- As with any medicine, diclofenac may cause side effects in some people. Most side effects are mild, but very rarely they can be serious.
- Research has shown that the risk of some heart and blood vessel problems may be higher with diclofenac (when taken by mouth) than with some alternative anti-inflammatories
- You should speak to your GP or pharmacist at your next routine appointment or visit if you are taking diclofenac (tables, capsules, or suppositories) and you have a condition such as heart failure, other heart disease (eg, angina), circulatory problems causing leg pain, or if you have had a heart attack or stroke. Your doctor or pharmacist will recommend an alternative treatment. Tell your doctor or pharmacist if you are taking any heart medicines, or have had any heart or circulatory problems in the past.
- You should always use the lowest dose of anti-inflammatory medicine that controls your symptoms, and stop taking the medicine if it is no longer needed. Do not take more than one type of anti-inflammatory medicine at the same time (for example, do not take ibuprofen and diclofenac at the same time). The risks are much lower with anti-inflammatory creams or gels.

### **Further information**

#### What is diclofenac?

Diclofenac is a type of non-steroidal anti-inflammatory drug (or 'NSAID'). Anti-inflammatory drugs are widely used important medicines in the treatment of arthritis and other conditions that cause pain and inflammation. Diclofenac, along with ibuprofen and naproxen, is among the most widely used anti-inflammatory medicines in the UK. There are various other anti-inflammatory medicines available—among them, newer, types called 'coxibs' (there are two: celecoxib and etoricoxib).

The main brand of diclofenac is Voltarol but it is also available as generic medicines or medicines for joint pain relief.



# What is the known safety profile of anti-inflammatory drugs?

As with all medicines, anti-inflammatory drugs such as diclofenac may cause side effects (adverse reactions) in some people. A full list of known side effects can be found in the patient information leaflet accompanying your medicine. Minor stomach or intestinal symptoms (such as pain, nausea, vomiting or diarrhoea) are among the most common problems; rarely (in less 1/1000 people) these effects can be more serious.

In recent years, research has shown that anti-inflammatory medicines may cause rare but potentially serious side effects on the heart and circulatory system. In particular, they may slightly increase the risk of heart attack or stroke. Your doctor or pharmacist will take these risks into account when advising on the right treatment for you. The newer coxib anti-inflammatories generally have a lower risk of stomach and intestinal side effects, but a higher risk of heart and circulatory side effects compared to the older NSAID anti-inflammatories.

### What is the new information and advice on using diclofenac?

The latest evidence continues to show that the benefits of diclofenac outweigh the risks; however, its heart and blood vessel risk appears to be similar to those for coxibs. As a result, your doctor and pharmacist will no longer recommend diclofenac for you, if you are at particular risk of some of these problems.

## What should I do if I'm taking diclofenac?

- You should speak to your GP or pharmacist at your next routine appointment or visit if you have
  a condition such as heart failure, other heart disease (eg, angina), circulatory problems causing
  leg pain, or if you have had a heart attack or stroke. Your doctor or pharmacist will recommend
  an alternative treatment. Diclofenac may no longer be suitable for you if you have significant risk
  factors for cardiovascular disease (such as high blood pressure, diabetes, or smoking) and so
  your doctor or pharmacist may consider an alternative treatment
- For many patients, diclofenac will continue to provide safe and effective pain relief and so your
  treatment may not need to change. However, the lowest effective dose of diclofenac should be
  used for the shortest duration necessary to control any symptoms. Therefore, your healthcare
  provider may periodically assess your pain relief and response to treatment and so it is
  important that you attend any scheduled routine appointments
- Speak to your healthcare provider (doctor, nurse or pharmacist) if you have any concerns about the new information about diclofenac
- You can continue to take diclofenac cream or gel as before, as the risks are much lower for diclofenac when it rubbed into the skin