

What does the black triangle mean?



The European Union (EU) has introduced a new way of identifying medicines that are being monitored particularly closely.

These medicines have a black inverted triangle displayed in their package leaflet, together with a short sentence that reads:

▼ **"This medicinal product is subject to additional monitoring."**

All medicines are carefully monitored after they are placed on the EU market. However, medicines with the black triangle are being monitored even more closely than others.

This is generally because there is less information available about them compared with other medicines, for example because they are new on the market.

It does not mean that the medicine is unsafe.

How to report side effects

You should report any suspected side effects with a medicine you are taking, particularly if it displays the black triangle.

You can report side effects to your doctor, pharmacist or nurse.

You can also report side effects directly to your national medicines regulator, using the reporting system in your country. Information on how to do this can be found in the package leaflet of your medicine or on your national medicines regulator's website.

By reporting side effects, you can help medicines regulators assess whether the benefits of a medicine remain greater than its risks.



Why are medicines monitored after they are approved?

European regulatory authorities decide to authorise medicines after assessing the results of laboratory tests and clinical trials.

Only medicines whose benefits have been shown to be greater than their risks can be marketed. This ensures that patients can access the treatments they need without being exposed to unacceptable side effects.

Clinical trials usually involve a limited number of patients for a defined time period in controlled conditions.

In a real-life setting, a larger and more diverse group of patients will use the medicine. They may have other diseases and they may be taking other medicines.

Some less common side effects may only be apparent when a medicine has been used for a long time by a large number of people.

It is therefore vital that the safety of all medicines continues to be monitored while they are on the market.

Examples of medicines under additional monitoring include new medicines authorised since the start of 2011 and medicines for which regulators require more studies to be carried out, e.g. on long-term use or on rare side effects seen in clinical trials.

Visit your national medicines regulator at:

www.mhra.gov.uk (United Kingdom)

www.imb.ie (Ireland)

www.medicinesauthority.gov.mt (Malta)

For more information, visit www.ema.europa.eu

