

MOLCAVA

(FERRIC CARBOXYMALTOSE)

Important Information for Patients About the Possible Risk of Serious Allergic Reactions with Molcava (medication given by needle into the vein)

Please read this leaflet carefully and discuss any questions you may have with your Doctor.



Please report side effects to the MHRA through the Yellow Card scheme. You can report via the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Side effects should also be reported to Viatris at pv.uk@viatris.com

Molcava (ferric carboxymaltose) Patient Educational Material

Molcava is used to treat iron deficiency when oral preparations are ineffective or cannot be used.

Molcava can cause allergic reactions and must be administered by persons trained to evaluate and manage these reactions.

In some patients these allergic reactions can become severe or life-threatening (known as anaphylactic reactions) and can cause problems with your heart and blood pressure and/or cause you to faint or lose consciousness.

You may have an increased risk of having an allergic reaction if you have:

- known allergies including drug allergies
- a history of severe asthma, eczema or other allergies (for example dust, pollen, pet dander) or
- immune or inflammatory conditions (e.g. rheumatoid arthritis, lupus erythematosus and others)

You should tell your doctor or nurse before they prescribe or give you Molcava

if you have any of these allergies or conditions.

Your Doctor will decide whether the benefit to you is greater than the risk.

You should not be prescribed or given Molcava if:

- you are allergic (hypersensitive) to the product or any of the other ingredients of this medicine
- you have experienced serious allergic (hypersensitive) reactions to other IV iron treatments in the past*
- you have iron overload (too much iron in your body)
- your anaemia is not caused by iron deficiency

You should tell your doctor or nurse before they prescribe / administer an Molcava if you have any of these allergies or conditions.

*** It is important to know that a reaction can still happen even if you have not had any problems in the past with Molcava.**

Pregnancy: Molcava should not be used during pregnancy unless clearly necessary. If you are pregnant or think you could be pregnant, it is important to discuss this with your doctor.

You should contact your Doctor or Nurse immediately if:

- you have any signs or symptoms of an allergic reaction during or shortly after treatment with Molcava

For example: hives or rash, itching, dizziness, light-headedness, swelling of the lips, tongue, throat or body, difficulty breathing, shortness of breath or wheezing.

- Your doctor or nurse will monitor you for signs and symptoms of an allergic reaction for at least 30 minutes after each time Molcava is given to you.

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