# **FORIDA-FCM Injection**

# COMPOSITION: Each 10 ml vial of FORIDA-FCM contains

Ferric Carboxymaltose 50 mg/ml Injection

# STORAGE

- Store below 25°C
- Store in a cool & dry place away from direct sunlight
- Keep it out of reach of children

# **PRODUCT INTRODUCTION**

Forida FCM Injection is an iron replacement medicine. It is used to treat a type of anemia where you have fewer amount of red blood cells due to insufficient iron in your body (iron-deficiency anemia). Iron is needed to produce the red blood cells that carry oxygen around your body.

Forida FCM Injection is given by injection or infusion (saline drip) into a vein by your doctor or nurse. You will be watched carefully to make sure you do not have an allergic reaction. It is usually given in two doses, seven days apart. Your doctor will decide how much and how often you may need injections to improve your anemia. Eating a well-balanced diet that has enough iron, vitamins, and minerals can help to replenish your iron reserves. Good sources of iron include meat, eggs, raisins, broccoli, and lentils.

The most common side effects include vomiting, headache, dizziness, high blood pressure, and pain or irritation at the site of injection. Most of these usually go away within a short time of the injection. If you are bothered by them or they go on for longer, talk to your doctor or nurse. You should not have this medicine if your anemia is not caused by a lack of iron.

Before taking it, tell your doctor if you have rheumatoid arthritis, asthma or other allergies, high blood pressure, or liver problems. This may affect your treatment. It is not known whether this medicine is safe for use if you are pregnant or breastfeeding so please take advice from your doctor. You will have tests to check your blood cells and iron levels, monitor your progress, and check for side effects. It may be advisable to limit alcohol during treatment.

# USES OF FORIDA FCM INJECTION

Treatment of Iron deficiency anemia

# **BENEFITS OF FORIDA FCM INJECTION**

# In Treatment of Iron deficiency anemia

Anaemia is a condition where your body does not have enough red blood cells to carry oxygen around your body. If you do not have enough iron from the foods you eat (because of poor nutrition or poor absorption of the mineral), your body will produce fewer red blood cells and can cause anaemia. Forida FCM Injection is an iron replacement product. It can boost your levels of red blood cells and reduce the symptoms of anaemia such as tiredness and weakness. This medicine is given as an injection by a doctor or nurse, usually in two doses 7 days apart. Make sure you attend all appointments. You should not have this medicine if your anaemia is not caused by a lack of iron.

# SIDE EFFECTS OF FORIDA FCM INJECTION

Most side effects do not require any medical attention and disappear as your body adjusts to the medicine. Consult your doctor if they persist or if you're worried about them

# Common side effects of Forida FCM

- Vomiting
- Nausea
- Dark colored stool
- Headache
- Dizziness
- High blood pressure
- Injection site reactions (pain, swelling, redness)

# HOW TO USE FORIDA FCM INJECTION

Your doctor or nurse will give you this medicine. Kindly do not self administer.

# HOW FORIDA FCM INJECTION WORKS

Forida FCM Injection is an anti-anemic medication. It replenishes the iron stores in your body. Iron is vital for the formation of new red blood cells and hemoglobin, a substance that gives these cells the ability to transport oxygen.

# SAFETY ADVICE



# CONSULT YOUR DOCTOR

It is not known whether it is safe to consume alcohol with Forida FCM Injection. Please consult your doctor.



Pregnancy

# CONSULT YOUR DOCTOR

Forida FCM Injection may be unsafe to use during pregnancy. Although there are limited studies in humans, animal studies have shown harmful effects on the developing baby. Your doctor will weigh the benefits and any potential risks before prescribing it to you. Please consult your doctor.



Breast feeding

# SAFE IF PRESCRIBED

Forida FCM Injection is safe to use during breastfeeding. Human studies suggest that the drug does not pass into the breastmilk in a significant amount and is not harmful to the baby.



#### SAFE

Forida FCM Injection does not usually affect your ability to drive.



Kidney

#### SAFE IF PRESCRIBED

Forida FCM Injection is probably safe to use in patients with kidney disease. Limited data available suggests that dose adjustment of Forida FCM Injection may not be needed in these patients. Please consult your doctor.



#### CAUTION

Forida FCM Injection should be used with caution in patients with liver disease. Dose adjustment of Forida FCM Injection may be needed. Please consult your doctor.

# WHAT IF YOU FORGET TO TAKE FORIDA FCM INJECTION?

If you miss a dose of Forida FCM Injection, please consult your doctor.

# **Quick tips**

- Forida FCM Injection is used for the treatment of iron deficiency, when oral iron preparations are ineffective or cannot be used.
- Your doctor or nurse will administer it by injection. You will be observed for at least 30
  minutes after each injection as it may cause allergic reaction.
- FCM should always be diluted in 0.9% Sodium Chloride solution (Normal Saline) only
- Concentration of FCM should not be less than 2mg/ml or more than 4 mg/ml.
- Your blood pressure and blood iron levels will be regularly monitored during treatment with this medication.
- Inform your doctor if you are taking any iron-containing products by mouth.
- Do not consume alcohol when on treatment with this medicine as it may worsen its side effects.
- It may cause your stools to become black or dark in color. This is normal and harmless.

# FAQs

Q. What precautions are required while administering Forida FCM Injection? Forida FCM Injection should be administered by staff that is trained in dealing with serious allergic reactions (anaphylactic reaction). Forida FCM Injection can be administered as an undiluted injection, directly into the vein or via a dialyzer if the patient is on dialysis. It can also be diluted with sodium chloride and given as infusion directly into the vein. The patient should be monitored for at least 30 minutes after each injection. Also, the injection should not be given below the skin (subcutaneous route) or in the muscle (intramuscular route).

Q. How should Forida FCM Injection vials be stored before use?

Forida FCM Injection vials should be stored at 20°C to 25°C (68°F to 77°F). Remember, these should not be freezed. The temperature should not deviate more than 15°C to 30°C (59°F to 86°F).

Q. How often can Forida FCM Injection be re-injected?

Usually, two doses of this medicine are given 7 days apart. The hemoglobin is then assessed at least 4 weeks after the final injection to allow time for the RBCs to form. If the reports still show deficiency of iron, it can be re-administered depending on individual need.

Q. Can Forida FCM Injection cause an increase in blood pressure?

Yes, Forida FCM Injection may cause a temporary increase in blood pressure accompanied with facial flushing, dizziness, and nausea. This may occur immediately after you take the medicine and generally disappears within 30 minutes.

Q. What should be done if leakage of Forida FCM Injection occurs?

Incorrect administration of Forida FCM Injection may cause leakage of the medicine at the administration site. The administration must be stopped immediately if there is some leakage. The leakage may cause skin irritation and long-lasting brown discoloration of skin at the administration site.

Q. Is Forida FCM Injection safe in pregnancy?

There is limited data on the use of Forida FCM Injection in pregnancy. It is important to tell your doctor if you are pregnant or are planning to have a baby. Consult your doctor if you become pregnant during treatment with Forida FCM Injection. Your doctor will decide whether you need to continue treatment or discontinue it