ESTYPLEX 5 VITAMIN B COMPLEX INJECTION

PATIENT INFORMATION LEAFLET (PIL)

ESTYPLEX-5 (Vitamin B Complex Injection)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

- 1. What Estyplex 5 is and what it is used for
- 2. What you need to know before you take Estyplex 5
- 3. How to take Estyplex 5
- 4. Possible side effects
- 5. How to store Estyplex 5
- 6. Contents of the pack and other information.

1. What Estyplex 5 is and what it is used for:

Estyplex 5 is a formulation which is a Vitamin B complex as injection.

Estyplex 5 When the dietary intake is inadequate or in pronounced deficiency states, B-Complex vitamins are prescribed. In defined cases of clinical deficiency, parenteral administration is recommended for quick recovery of health and wellbeing.

2. What you need to know before you take Estyplex 5

Do not take Estyplex 5:

No known contraindications have been indicated so far for the use of B-complex vitamins. However, a few persons are hypersensitive to thiamine. The most frequent reactions of hypersensitivity to vitamin B1 are anaphylaxis, dyspnoea or bronchospasm. A test dose may be given before vitamin B1 is administered parenterally.

Warnings and precautions

Talk to your doctor or pharmacist before taking Estyplex 5

Hypersensitivity to vitamin B1 should be excluded before parenteral therapy is instituted. Special care should be taken of patients with known allergic disposition. Pyridoxine can decrease efficacy in patients with levodopa, in patients with parkinsonism, should not be used for primary treatment of specific vitamin deficiency.



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Other medicines and Estyplex 5

Drug interactions with vitamins are rare and have not been reported. In fact, they are given as nutritional supplements during drug therapy especially when treating with antibiotics. During treatment with isoniazid, a deficiency state of vitamin B6 may occur and hence this vitamin is given during the period.

Pregnancy and breast-feeding

Not Known.

Driving and using machines

Not Known.

Estyplex 5 contains lactose?

Estyplex 5 does not contain Lactose.

3. How to take Estyplex 5

Posology: The required quantity (1-2 ml) should be administered

Method of administration: Can be given by very slow I.V. or through a drip.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.

Rarely, hypersensitivity reactions to vitamin B1 may occur following parenteral administration of Estyplex-5 injection leading to skin rash, itching or even anaphylaxis involving nausea, vomiting, bronchospasm and circulatory collapse.

5. How to store Estyplex 5

Keep this medicine out of the sight and reach of children.

Store below 30°C. Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Estyplex 5 contain:

The **active substance** in Estyplex 5 is Thiamine hydrochloride, Riboflavin (as Riboflavin Sodium Phosphate), Pyridoxine hydrochloride, Dexpanthenol, Nicotinamide,



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The other ingredients are:

Benzyl alcohol (as preservative), EDTA disodium, Polysorbate 80, Water for injection.

What Estyplex 5 injection look like and contents of the pack:

A clear yellow coloured solution

Estyplex 5 is supplied in the pack of: In 10 ml USP Type I Amber vial sealed with plug and Aluminium seal.

Marketing Authorisation Holder

TIL HEALTH CARE PVT LTD.

"Jhaver Centre Rajah Annamalai Building, 72, Marshalls road, Egmore, Chennai 600008.INDIA

Manufacturer

M/S. TABLETS (INDIA) LIMITED.

No.179, T.H. Road , Chennai – 600081.INDIA