Phenobarbital Sodium

15mg/ml, 30mg/ml, 60mg/ml or 200mg/ml Injection

Phenobarbital Sodium

(Referred to as Phenobarbital Injection in this leaflet)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you. If you have any further questions, please ask your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Phenobarbital Injection is and what it is used for
2. What you need to know before you are given Phenobarbital Injection
3. How Phenobarbital Injection will be given
4. Possible side effects
5. Contents of the pack and other information

What is Phenobarbital Injection?

Phenobarbital Injection is used in the treatment of most types of epilepsy except absence seizures (petit mal).

What do you need to know before you are given Phenobarbital Injection?

You should not be given Phenobarbital Injection if:

- You are allergic (hypersensitive) to any barbiturates or any of the other ingredients in this medicine (see section 6).
- You have had an allergic reaction to Phenobarbital before.
- You are at risk of developing drug-induced liver disease.
- You take, or have recently taken, St John's Wort.
- You are pregnant, planning to become pregnant or are breast-feeding.
- You have any of the following conditions:
  - a syndrome called antiepileptic hypersensitivity syndrome.
  - a syndrome called Stevens-Johnson syndrome, toxic epidermal necrolysis.
  - You have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Phenobarbital Injection.
- You are at risk of developing drug-induced liver disease.

If any of the side effects get serious, or you notice any side effects not listed in this medicine, please tell your doctor.

How to report side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.yellowcard.gov.uk. By reporting side effects you can help provide more information on the safety of new medicines.

1. How to store Phenobarbital Injection

Keep out of the sight and reach of children.

Phenobarbital Injection should be kept in the outer carton in order to protect from light. Do not store above 25°C.

Do not use Phenobarbital Injection after the expiry date which is stated on the ampoule label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

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

2. Contents of the pack and other information

What Phenobarbital Injection contains

The active ingredient is Phenobarbital Sodium.

Phenobarbital Injection is a sterile solution.

- Phenobarbital Injection 15mg/ml contains 15mg of Phenobarbital Sodium.
- Phenobarbital Injection 30mg/ml contains 30mg of Phenobarbital Sodium.
- Phenobarbital Injection 60mg/ml contains 60mg of Phenobarbital Sodium.
- Phenobarbital Injection 200mg/ml contains 200mg of Phenobarbital Sodium.

What are the other ingredients?

- Propylene glycol, Disodium Edetate and Water for Injection.

What Phenobarbital Injection looks like and contents of the pack

Each ampoule contains 1 ml of Phenobarbital Injection.

Phenobarbital Injection is supplied to your pharmacist or doctor in packs of 10 clear glass ampoules.

Marketing Authorisation Holder and Manufacturer

Martindale Pharmaceuticals Ltd, Rampton Road, Hardle Hill, Ryden, MK3 1RG, United Kingdom.

Product Licence Number

- Phenobarbital Injection 15mg/ml: PL 01883/6161 R.
- Phenobarbital Injection 30mg/ml: PL 01883/6189 R.
- Phenobarbital Injection 60mg/ml: PL 01883/5109 R.
- Phenobarbital Injection 200mg/ml: PL 01883/3109 R; PK 4562 R

This leaflet was last revised in January 2018.