

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Epanutin 100mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Phenytoin Sodium 100mg

Excipients: lactose monohydrate

For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from Spain:

Hard gelatine capsule with a white opaque body and orange cap, marked 'Epanutin 100' on cap and body

4 CLINICAL PARTICULARS

As per PA0822/011/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/011/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Lactose Monohydrate
Magnesium Stearate

Shell:

Gelatin (E441)
Titanium Dioxide (E171)
Erythrosine (E127)
Sodium Lauryl sulfate
Quinolone Yellow (E104)

Printing ink:

Shellac
Black iron oxide (E172)
N-Butyl alcohol
Propylene glycol
dehydrated alcohol
Isopropyl alcohol
Ammonium hydroxide
Water

Or
Shellac
Dehydrated alcohol
Isopropyl alcohol
Butyl alcohol
Propylene glycol
Concentrated ammonium solution
Black iron oxide (E172)
Potassium hydroxide
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the bottle and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Epanutin is available in packs containing 100 capsules.
The capsules are packed in a white plastic container with a white plastic cap and a tamper evident seal.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2 North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/165/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2011

10 DATE OF REVISION OF THE TEXT

June 2017