Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Epanutin 100 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg phenytoin sodium.

Excipient(s) with known effect
Lactose Monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule

Product imported from Spain and Greece:
A white powder in a No 3 hard gelatin capsule with a white opaque body and orange cap, radially imprinted 'EPANUTIN 100'.

4 CLINICAL PARTICULARS

As per PA23055/003/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/003/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Magnesium stearate

Shell:
Gelatin (E441)
Erythrosine (E127)
Quinolone yellow (E104)
Titanium dioxide (E171)
Sodium laurilsulfate

Printing inks:
UK product:
Shellac
Black iron oxide (E172)
Propylene glycol
It may also contain potassium hydroxide.

Spanish product:
Colour code 10A1
Shellac in ethanol
Black iron oxide (E172)
N-Butyl alcohol
Dehydrated alcohol

Isopropyl alcohol
Propylene glycol
Ammonium hydroxide 28%
Purified water
OR
Colour code 1014
Shellac
Dehydrated alcohol
Isopropyl alcohol
Butylated alcohol
Propylene glycol
Concentrated ammonium solution
Black iron oxide (E172)
Potassium hydroxide
Purified water

Greek Product:
Shellac Glaze ~ 45% in ethanol
Black iron oxide
N-butyl alcohol
Purified water,
Propylene glycol
Anhydrous ethanol
Isopropyl alcohol
Ammonium hydroxide (28%)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date on the container of the product in the country of origin.

6.4 Special precautions for storage

Do not store above 25 ºC.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

White container with white cap containing 84 or 100 capsules and a desiccant, packaged in an outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/244/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2011

10 DATE OF REVISION OF THE TEXT

July 2022