

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol 500 mg Film Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg paracetamol.

Excipients with known effect:

Sodium methyl parahydroxybenzoate (E219)

Sodium ethyl parahydroxybenzoate (E215)

Sodium propyl parahydroxybenzoate (E217)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Czech Republic

White capsule shaped film coated tablet with convex edges and debossed with a “p” within a circle on one face and a break line on the other. The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0678/107/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0678/107/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch

Calcium carbonate

Alginic acid

Crospovidone type A

Povidone 25

Magnesium stearate

Colloidal anhydrous silica

Parahydroxybenzates (Sodium ethyl parahydroxybenzoate (E215), Sodium propyl parahydroxybenzoate (E217) and Sodium methyl parahydroxybenzoate (E219))

Carnauba wax

Opadry white YS-1-7003 (titanium dioxide, hypromellose, macrogol and polysorbate 80)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage precautions.

6.5 Nature and contents of container

PVC/Aluminium foil blister strips packed into cardboard cartons containing 24 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th May 2017

10 DATE OF REVISION OF THE TEXT

May 2018