

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zydol 50 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 50mg tramadol hydrochloride.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.
Product imported from the United Kingdom:
Yellow/yellow shiny hard gelatine capsules.

4 CLINICAL PARTICULARS

As per PA1189/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1189/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsules contents:
Microcrystalline cellulose
Sodium starch glycolate
Magnesium stearate
Colloidal anhydrous silica

Capsule shell:
Gelatine
Sodium Laurilsulfate
Yellow iron oxide (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C
Store in the original container.

6.5 Nature and contents of container

PVC/foil blister strips in a cardboard carton. Pack size 100 capsules.

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
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 27th July 2007

Date of Last Renewal: 27th July 2012

10 DATE OF REVISION OF THE TEXT

September 2014