SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE FINISHED PRODUCT

Pengesic SR Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Tramadol Hydrochloride	100

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

White, round, transparent film-coated tablet with shallow convex faces and 'Hovid' embossed on one face.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

- Pengesic SR tablet is indicated for the treatment of moderate to severe pain.

4.2 Posology and Method of administration

Oral

The dosage should be adjusted to the intensity of the pain and the sensitivity of the individual patient. Unless otherwise prescribed, Pengesic SR tablet 100mg should be taken as follows - with or without meals:

Single dose for adults and adolescents over 12 years of age:
1-2 capsules (100-200mg tramadol hydrochloride) should be swallowed whole (not divided or chewed) with sufficient liquid, preferably mornings and evenings. If in severe pain the analgesic demand is likely to higher, 2 tablets (200mg tramadol hydrochloride) can be taken as initial dose. The lowest analgesically effective dose should generally be selected. Daily doses of 400mg tramadol hydrochloride should not be exceeded, except in special clinical circumstances. The dosage interval should not be less than 8 hours.

Children:
On account of the dosage strength, Pengesic SR tablet 100mg are not recommended for children below the age of 12 years.

Geriatric patients:
In acute pain a dosage adjustment is not necessary as Pengesic SR tablet 100mg is given only once or a few times. In chronic pain a dosage adjustment is usually not necessary in elderly patients (up to 75

years) with no clinically manifest hepatic or renal insufficiency. In old patients (above the age of 75 years) elimination may be prolonged. Therefore, if necessary the dosage intervals are to be extended according to the patient's requirements.

Hepatic and renal insufficiency/dialysis:
In acute pain a dosage adjustment is not necessary as Pengesic SR tablet 100mg is given only once or a few times. In patients with severe renal and/or hepatic insufficiency Pengesic SR tablet 100mg should not be administered. In less severe cases prolongation of the dosage interval should be considered.

Duration of Treatment:
Pengesic SR tablet 100mg must not be given for longer than therapeutically absolutely necessary. If long-term pain treatment is necessary, checks should be carried out at regular and brief intervals (if necessary with breaks in treatment) as to whether and in what doses further treatment with Pengesic is necessary.

4.3 Contraindication

It is generally contraindicated in the following conditions:

- respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion.
- in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised.
- it should not be used in patients receiving MAO inhibitors.
- previous hypersensitivity to Pengesic.
- it should not be used during pregnancy.
- it should not be administered during lactation as tramadol and its metabolites have been detected in breast milk.

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4.4 Special warnings and precautions for use

It should be used with extreme caution in patients with the following conditions:

- Decreased respiratory reserves; and should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease, hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy, shock or inflammatory or obstructive bowel disorders, myasthenia gravis.
- It should be given with great care to infants, especially neonates.
- The administration of opioid analgesics during labour may cause respiratory depression in the newborn infant.
- Even when administered according to instructions, the preparations may affect the reaction ability of the patients to such an extent that his capacity to drive or operate machines may be impaired. This applies particularly in conjunction with alcohol.
- Information for the patients:
  Pengesic is a potent drug for the relief of pain, e.g. in wound pain, fractures, severe nerve pain, tumour pain, heart attack. It should not be used for minor pain. The effect sets in quickly and lasts for some hours.Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

- It should be given with extreme caution in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- The depressant effects of Pengesic are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, tricyclic anti depressants and phenothiazines.
- Opioid analgesics with some antagonist activity such as buprenorphine, butorphanol, nalbuphene or pentazocine may precipitate withdrawal symptoms in patients who have recently used pure agonists such as Pengesic.
- On the concomitant administration of Pengesic with substances which also act on the central nervous system (e.g tranquillizers, hypnotics) the sedative effects (fatigue) may be intensified. At the same time, however, combining Pengesic with a tranquillizer, for example, will probably have a favourable effect on the pain sensation. Pengesic should not be used in patients receiving MAO inhibitors.

4.6 Pregnancy and lactation

- It should not be used during pregnancy.
- It should not be administered during lactation as tramadol and its metabolites have been detected in breast milk.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable Effects

- Tramadol can produce drug dependence of the mu-opioid type and may potentially be abused. Tolerance development, drug-seeking behavior and craving have been associated with the use of tramadol.
- The commonest side effects include abdominal or stomach pain,anorexia,asthenia, central nervous system(CNS) stimulation, constipation, diarrhea, dizziness or vertigo, drowsiness, dry mouth, dyspepsia, headache, nausea, pruritus, skin rash, sweating and vomiting.

4.9 Overdose

Clinical features:

Cold, clammy skin; confusion; convulsions; severe dizziness; severe drowsiness; pinpoint pupils of eyes; slow heartbeat; slow or troubled breathing; unconsciousness; severe weakness.

Treatment:

Intensive supportive therapy may be required to correct failure and shock. In addition, the specific antagonist naloxone hydrochloride is used to counteract very rapidly the severe respiratory depression and coma produced by excessive doses of opioid analgesics. A dose of 0.4 to 2 mg is given by intravenous injection, repeated at intervals of 2 to 3 minutes if necessary, up to 10 mg. Naloxone may also be given by subcutaneous or intramuscular injection or by intravenous infusion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tramadol is a centrally-acting analgesic that is not chemically related to opiates. The mechanism of action of tramadol has not been fully determined, but it may bind to mu-opioid receptors and inhibit the reuptake of norepinephrine (NE) and serotonin. The ability of tramadol to inhibit the neuronal uptake of monoamines in the same concentration range at which it binds to mu-opioid receptors differentiates it from typical opioids.

5.2 Pharmacokinetic properties

Absorption: Tramadol is readily absorbed after oral doses but is subject to first-pass metabolism. Mean absolute bioavailability of 100-mg dose is approximately 75%. The rate or extent of absorption is not significantly affected by administration with food.

Distribution: Tramadol is widely distributed, crosses the placenta, and appears in small amounts in breast milk.

Protein Binding: Low (20%)

Biotransformation: Tramadol is metabolized by N- and O-demethylation via the cytochrome P450 isoenzymes CYP3A4 and CYP2D6 and glucuronidation or sulfation in the liver. The metabolite O-des-methyltramadol is pharmacologically active. The inactive metabolites are formed by N-demethylation.

Elimination: Tramadol is excreted mainly in the urine, predominantly as metabolites. The elimination half life after oral doses is about 6 hours.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Silicon Dioxide
Magnesium Stearate
Copovidone
Hydroxypropyl Methylcellulose K-15MCR
Lactose Monohydrate
Microcrystalline Cellulose
Isopropyl Alcohol
Polyethylene Glycol 4000
Hydroxypropyl Methylcellulose E-5
Hydroxypropyl Methylcellulose E-15

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture

6.4 Special precaution for storage

Store below 30˚C. Protect from light and moisture.

6.5 Nature and contents of container

Immediate Container/Packaging

Primary Packaging

Blister Pack

Type

Push-through blister pack; the package consists of a clear thermoformable plastic (PVDC) material and a heat-sealed, lacquered backing material.

Material description	:	PVDC coated Polyvinylchloride(PVC) Film
Appearance	:	Glass clear transparent film
Aluminium blister foil		
Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface/Aluminium foil with high slip primer on matt surface and heat seal bright surface
Appearance	:	Bright surface/Matt surface each side

Secondary Packaging Components

Outer Container/Packaging

Type: Unit box, Package Insert & Plain Carton for Pengesic SR Tablet

Material: Paper carton

6.6 Special precautions for disposal and other handling

NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER ADDRESS

Name : HOVID Bhd.

Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer Name :

Name : HOVID Bhd.

Address : Lot 56442, 7 ½ Miles,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak., Malaysia.

8. MARKETING AUTHORISATION NUMBER

HOV/MAL/130

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE AUTHORISATION

September 2017

10. DATE OF REVISION OF THE TEXT

January 2017