SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE FINISHED PRODUCT

Setrof Tablet 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Sertraline Hydrochloride *(Equivalent to Sertraline 50mg)*	56 mg

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

Oblong, white to off white film-coated tablet, shallow convex with break bar on one side and HD embossed on the other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

For treatment of symptoms of depression including depression accompanied by symptoms of anxiety. For treatment of obsessions and compulsions in patients with obsessivecompulsive disorder (OCD). For treatment of panic disorder with or without agoraphia.

4.2 Posology and Method of administration

Route of administration is oral.

Adults

• Depression (including accompanying symptoms of anxiety):

The starting dose is 50 mg daily and the usual antidepressant dose is 50 mg daily. In some patients, doses higher than 50 mg may required.

• Obsessive Compulsive Disorder:

The starting dose is 50 mg daily, and the therapeutic dose range is 50-200 mg daily.

• Post-Traumatic Stress Disorder:

Treatment for PTSD should be initiated at 25 mg/day. After one week, the dose should be increased to 50 mg once daily. PTSD is a heterogeneous illness and some patient groups fulfilling the criteria for PTSD do not appear to be responsive to treatment with Setrof Tablet. Dosing should be reviewed periodically by the prescribing physician to determine response to therapy and treatment should be withdrawn if there is no clear evidence of efficacy.

Use in children aged 6 - 17 years

Treatment should only be initiated by specialists.

4.3 Contraindication

Concomitant use of monoamine oxidase inhibitors (MAOIs) with sertraline is contraindicated.

4.4 Warnings and precautions

- Not taking sertraline with or within 14 days of taking an MAO inhibitor, not taking an MAO inhibitor within 14 days of taking sertraline.
- Avoiding use of alcohol beverages.
- Possible drowsiness, impairment of judgement, thinking, or motor skills

Risk benefits should be considered when the following medical problems exist:

- Hepatic function impairment
- History of mania
- Neurological impairment, including development delay
- Renal function impairment
- Seizure disorders
- Sensitivity to sertraline
- Weight loss
-

4.5 Drug Interactions

- Concurrent use of MAO inhibitors with sertraline may result
- in hyperpyretic episodes, severe convulsions, hypertensive crises, or the serotonin syndrome; fatalities have occurred.
- Sertraline may inhibit the metabolism of tricyclic (TCAs).
- Concurrent use of terfenadine with sertraline may increase the risk of cardiac arrhythmias.
- Concurrent use of a highly protein-bound drug (e.g. digitoxin and warfarin) with sertraline may lead to increased plasma concentration of free medications and increased risk of adverse effects.
- Concurrent use of lithium with sertraline may lead to an increased incidence of serotonin-associated side effects.

4.6 Pregnancy and lactation

Pregnancy:

Although animal studies did not provide any evidence of teratogenicity, the safety of Setrof Tablet during human pregnancy has not been established. As with all drugs Setrof Tablet should only be used in pregnancy if the potential benefits of treatment to the mother outweigh the possible risks to the developing foetus.

Lactation:

Setrof Tablet is known to be excreted in breast milk. Its effects on the nursing infant have not yet been established. If treatment with Setrof Tablet is considered necessary, discontinuation of breast feeding should be considered

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Main Side/ Adverse Effects

In paediatric OCD patients, side-effects which occurred significantly more frequently with sertraline than placebo were: headache, insomnia, agitation, anorexia, tremor. Most were of mild to moderate severity

4.9 Overdose

Acute overdose of sertraline may develop the serotonin syndrome, anxiety, drowsiness, electrocardiogram (ECG) changes, mydriasis, nausea, tachycardia and vomiting.

Administrating activated charcoal to decrease the absorption of sertraline.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sertraline is a potent and selective inhibitor of neuronal uptake of serotonin (5-hydroxytryptamine [5-HT]). It has very weak effects on neuronal uptake of norepinephrine and dopamine. Chronic administration of sertraline in animals has resulted in down-regulation of postsynaptic beta-adrenergic receptors.

Sertraline lacks affinity for adrenergic (alpha1, alpha2, or beta) receptors, muscarinic – cholinergic receptors, gamma aminobutyric acid (GABA) receptors, dopaminergic receptors, histaminergic receptors, serotonergic (5-HT1A, 5-HT1B, 5-HT2) receptors, and benzodiazepine receptors. Sertraline does not inhibit monoamine oxidase.

5.2 Pharmacokinetic properties

Sertraline is slowly absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 4.5 to 8.5 hours after ingestion. Elimination half time of sertraline is reported to be 24 to 26 hours. Both sertraline and its metabolites are extensively distributed into body tissues. About 98% is bound to plasma proteins. Sertraline undergoes extensive first-pass metabolism in the liver. The main pathway is demethylation to N-desmethylsertraline which is inactive. Both sertraline and N-desmethylsertraline undergo oxidative deamination and subsequent reduction, hydroxylation and glucuronide conjugation. About 40 to 45% of an administered dose is excreted in the urine and faeces in 9 days, with less than 0.2% recovered unchanged in urine and 12% to 14% unchanged sertraline in faeces.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl Methylcellulose E-5
Dicalcium Phosphate Dihydrate
Microcrystalline Cellulose pH102
Magnesium Stearate
Sodium Starch Glycolate
Colloidal Silicone Dioxide
Hydroxypropyl Methylcellulose E-15
Isopropyl Alcohol (IPA)
Propylene Glycol
Talc
Titanium Dioxide
Purified water

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.

6.5 Nature and contents of container

Immediate Container/Packaging

Primary Packaging

Blister pack

Type

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

Rigid PVC Film

Colour Film	:	White Opaque
Material descrition	:	Rigid PVC Film

Aluminium blister foil

Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface
Appearance	:	Bright surface/Matt surface each side

Outer Container / Secondary Packaging

Outer Container/Packaging

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

6.6 Instructions for use and handling <and disposal>

NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER

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. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

HOV/MAL/4654

9. DATE OF FIRST AUTHORISATION

2018

10. DATE OF REVISION OF THE TEXT

January 2019