SUMMARY OF PRODUCT CHARACTERISTICS

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PRODUCT

Hovid Lipiduce-20 Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Atorvastatin Calcium	21.70

Kindly refer to Section 6.1 for excipient.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Atorvastatin is indicated:

As an adjunct therapy to diet to reduce elevated total cholesterol, LDL-cholesterol, apolipoprotein B, triglycerides and increase HDL- cholesterol in patients with:

- Primary hypercholesterolemia (heterozygous familial and nonfamilial).
- Combined hyperlipidemia (Fredrickson Types IIa and IIb).
- Hypertriglyceridemia (Fredrickson Type IV).
- Primary dysbetalipoproteinemia (Fredrickson Type III).

As an adjunct therapy with other lipid lowering treatment (e.g. LDL apheresis) in homozygous familial hypercholesterolemia to reduce total cholesterol and LDL cholesterol.

4.2 Posology and Method of administration

Oral

Usual Adult and adolescent dose:

Oral, the recommended initial dose of atorvastatin is 10 mg once daily which may be adjusted at intervals of 4 weeks. The dosage range is 10 to 80 mg once daily.

Usual pediatric dose:

Dosage has not been established.

The patient should be placed on a standard cholesterol-lowering diet and weight reduction programs/exercises before receiving atorvastatin and should continue the regimen during treatment with atorvastatin.

4.3 Contraindication

- Active liver disease or unexplained persistent elevations of serum transaminases.
- Hypersensitivity to any component of this drug
- Pregnancy and lactation.

.

4.4 Special warnings and precautions for use

- Liver Dysfunction: HMG-CoA reductase inhibitors have been associated with biochemical abnormalities of liver function. Therefore, liver function tests should be performed prior to and at 12 weeks following initiation of therapy or elevation in dose, and semiannually thereafter.
- Atorvastatin should be used with caution in patients with alcoholism, organ transplant with immunosuppressant therapy and/or patients who have a history of liver disease.
- Serious conditions such as hypotension, severe acute infection, severe metabolic, endocrine, or electrolyte disorder, uncontrolled seizures, major surgery, or trauma may increased risk of secondary renal failure if rhabdomyolysis occurs.

4.5 Interaction with other medicinal products and other forms of interaction

- The risk of myopathy increased with concurrent administration of cyclosporine, fibric or azole antifungals.
- Co-administration with antacid reduces plasma concentrations of atorvastatin by approximately 35%.
- Concurrent use of atorvastatin with cholestyramine or colestipol may decrease the bioavailability of atorvastatin.
- Concurrent use with digoxin may cause an elevation in serum digoxin concentration.
- Concurrent use with anticoagulants, coumarin- or indandione derivative may increase bleeding or prothrombin time.
- Concurrent use with large amounts of grapefruit juice has been reported to the plasma concentration-time curve (AUC).
- Co-administration of atorvastatin with an oral contraceptive may increase AUC value for norethindrone and ethinyl estradiol by approximately 30% and 20% respectively.
- Plasma concentrations of atorvastatin increased with co-administration of erythromycin.
- Caution should be exercised when if an HMG-CoA reductase inhibitor is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

4.6 Pregnancy and lactation

Atorvastatin is not recommended during pregnancy, in women who plan to become pregnant in the near future, or during lactation.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable Effects

Myalgia, myositis, rhabdomyolysis, constipation, diarrhea, heartburn, stomach pain, dizziness, headache, nausea, skin rash, insomnia.

4.9 Overdose

There is no specific treatment of atorvastatin overdosage. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atorvastatin is a selective, competitive inhibitor of 3-Hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase. The inhibition of HMG-CoA reductase prevents conversion of HMG-CoA to mevalonate, the rate-limiting step in cholesterol biosynthesis. Inhibition of cholesterol synthesis in the liver leads to upregulation of low-density lipoprotein (LDL) receptors and an increase in catabolism of LDL cholesterol. It may also reduce the production of LDL as a result of inhibition of hepatic synthesis of very low-density lipoprotein (VLDL), the precursor of LDL.

HMG-CoA reductase inhibitors reduce LDL-cholesterol, VLDL-cholesterol, and to a lesser extent, plasma triglyceride concentrations, and slightly increase high-density lipoprotein (HDL) concentration.

5.2 Pharmacokinetic properties

Atorvastatin is rapidly absorbed after oral administration; maximum plasma concentration occurs within 1 to 2 hours. It has low absolute bioavailability of about 12% due to presystemic clearance in the gastrointestinal mucosa and / or first-pass metabolism in the liver, its primary sites of action.
Atorvastatin is 98% bound to plasma proteins. It is metabolized by ortho-and parahydroxylation and beta-oxidation to active metabolites. The drug and its metabolites are eliminated primarily in the bile. The mean plasma elimination half-life is approximately 14 hours.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Polyvinylpyrrolidone
Calcium Carbonate
Croscarmellose Sodium
Lactose Monohydrate
Microcrystalline Cellulose
Magnesium Stearate
Propylene Glycol
Talc
Titanium Dioxide
Hydroxypropyl Methylcellulose E-5
Hydroxypropyl Methylcellulose E-15

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

2.5 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 Closure System / Primary 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.

Cold-form blister foil

Description	:	Multilayer cold-form aluminium-based blister foil, with a composition comprising nylon/Aluminium/PVC
Appearance	:	Bright surface/Matt surface each side

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 on bright surface
Appearance	:	Bright surface/Matt surface each side

Outer Container / Secondary Packaging

Outer Container/Packaging

Type: Unit box, Package Insert & Plain Carton for Hovid-Lipiduce 20 Tablet

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/222

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE AUTHORISATION

January 2018

10. DATE OF REVISION OF THE TEXT

October 2017