SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PRODUCT

Diabetmin 1000 mg Film-Coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Metformin Hydrochloride	1000 mg
For excipients, see 6.1	

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Metformin is used in the treatment of non-insulin-dependent diabetes mellitus (type 2) in adults, not responding to exercise and dietary modification. Diabetmin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

4.2 Posology and Method of administration

Mode of administration: Oral
Monotherapy and combination with other oral antidiabetic agents:
Usual adult dose:
Diabetmin 1000 mg Tablet : Initial dose of one tablet once daily with or after meals.

If necessary, medication can be increased gradually to a maximum of 3g daily.
If transfer from another oral antidiabetic agent is intended; discontinue the other agent and initiate metformin at the dose indicated above.

Combination with insulin:
Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin is given at the usual starting dose of one tablet 2-3 times daily while insulin dosage is adjusted on the basis of blood glucose measurements.

Usual children dose : Metformin is not recommended for use in children.

Usual geriatric dose : Please refer to adult dose.
(Due to potential for decreased renal function, the dosage should adjusted based on renal function and maximum doses are not advised for use in the elderly.)

Contraindication

This medication is contraindicated in patients with the following medical problems:

- Hypersensitivity to metformin.
- Any condition needing close blood glucose control, such as: severe burns, dehydration, diabetic
- Conditions associated with hypoxemia, such as: cardiorespiratory insufficiency, cardiovascular collapse, congestive heart failure, acute myocardial infarction.
- Severe, acute, or chronic hepatic disease.
- Active or history of lactic acidosis.
- Renal function impairment or renal disease.
- Diagnostic or medical examinations using intravascular iodinated contrast media such as: angiography, intravenous cholangiography, computed tomography (CT) scan, pyelography and urography.

Warnings and precautions

Lactic Acidosis:

Lactic acidosis is a rare, but serious (high mortality in the absence of prompt treatment), metabolic complication that can occur due to metformin accumulation. Reported cases of lactic acidosis in patients on metformin have occurred primarily in diabetic patients with significant renal failure. The incidence of lactic acidosis can and should be reduced by assessing also other associated risk factors such as poorly controlled diabetes, ketosis, prolonged fasting, excessive alcohol intake, hepatic insufficiency and any condition associated with hypoxia.

Diagnosis: Lactic acidosis is characterized by acidosis dyspnea, abdominal pain and hypothermia followed by coma. Diagnostic laboratory findings are decreased blood pH, plasma lactate levels above 5 mmol/L, and an increased anion gap and lactate/pyrute ratio. If metabolic acidosis is suspected, metformin should be discontinued and the patient should be hospitalized immediately.

Renal Function:

As metformin is excreted by the kidney, serum creatinine levels should be determined before initiating treatment and regularly thereafter:

- at least annually in patients with normal renal function;
- at least 2 to 4 times a year in patients with serum creatinine levels at the upper limit of normal and in elderly subjects.

Decreased renal function in elderly subjects is frequent and asymptomatic.

Special caution should be exercised in situations where renal function may become impaired, for example when initiating antihypertensive therapy or diuretic therapy and when starting therapy with an NSAID.

Administration of iodinated contrast agent: As the intravascular administration of iodinated contrast materials in radiologic studies can lead to renal failure, metformin should be discontinued prior to, or at the time of the test and not reinstituted until 48 hours afterwards, and only after renal function has been re-evaluated and found to be normal.

Surgery:
Metformin should be discontinued before elective surgery with general anaesthesia and should not be usually resumed earlier than 48 hours afterwards.

Other precautions:
- All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.
- The usual laboratory tests for diabetes monitoring should be performed regularly.
- Metformin alone never causes hypoglycaemia, although caution is advised when it is used in combination with insulin or sulfonylureas.

Drug Interactions

Concurrent use of this medication with the following may interact with metformin:
- Acute or chronic ingestion of alcohol.
- Cimetidine or other cationic medications excreted by renal tubular transport.
- Furosemide.
- Hyperglycemia-causing and hypoglycemia-causing medications.

4.6 Pregnancy and lactation

For fertility and pregnancy problems, adequate and well-controlled studies in humans have not been done and documented. For patient plans to become pregnant or during pregnancy, control of blood glucose with diet alone or a combination of diet and insulin is recommended, while use of metformin is discouraged. Metformin is distributed into breast milk, but safety for use in nursing mothers has not been established.

Effects on ability to drive and use machines

NOT APPLICABLE

Main Side/ Adverse Effects

Metformin can cause:
- Gastrointestinal adverse effects including anorexia, diarrhea, dyspepsia, flatulence, nausea, vomiting.
- Headache, metallic taste, weight loss.
- Anemia, megaloblastic, hypoglycemia, lactic acidosis.
- Long-term metformin therapy may cause a decrease of vitamin B12 absorption with decrease of serum levels.

Overdose

Symptoms of overdose: Hypoglycemia and lactic acidosis.
Treatment of overdose:
- For hypoglycemia: Treating with immediate ingestion of a source of glucose and counseling patient to obtain emergency medical assistance immediately.
- For lactic acidosis: Hemodialysis with sodium bicarbonate.

5.1 Pharmacodynamic properties

Metformin is an oral biguanide antidiabetic agent. Its mode of action is thought to be multifactorial and includes delayed uptake of glucose from the gastro-intestinal tract; increased peripheral glucose utilization mediated by increased insulin sensitivity; and inhibition of increased hepatic and renal gluconeogenesis.

5.2 Pharmacokinetic properties

Metformin Hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract. The absolute bioavailability of a single 500mg dose is reported to be about 50 to 60%, although this is reduced somewhat if taken with food. Plasma protein binding is negligible. It is excreted unchanged in the urine. The plasma elimination half-life is reported to range from about 2 to 6 hours after oral administration.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

List of excipeints

Polyvinylpyrrolidone
Microcrystalline cellulose
Pregelatinised Starch
Sodium Starch Glycolate
Magnesium Stearate
Hydroxypropyl methylcellulose
Polyethylene Glycol

Incompatibilities

NOT APPLICABLE

Shelf life

3 years from date of manufacture

Special precaution for storage

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

Nature and contents of container

Blister Pack

Type	:	Push-through blister pack; the package consists of a transparent themoformable plastic material and a heat-sealable lacquered backing material.
Material	:	Thermoformable plastic material : Polyvinyl Chloride (PVC) Backing Material : Aluminium Foil

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/0032

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

May 2017

10. DATE OF REVISION OF THE TEXT

January 2018