SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name
Perilon

1.2 Strength
Prednisolone 5 mg

1.3 Pharmaceutical Dosage Form
Tablet

2-Quality and Quantitative Composition:

ACTIVE INGREDIENTS	PER TABLET (MG)
Prednisolone	5 mg

For excipients, see 6.1

3-Pharmaceutical Form:

Round, white uncoated tablet, shallow convex faces; "HD" embossed and scored on the same face.

4-Clinical Particulars

4.1 Therapeutic indications

Prednisolone is used in the treatment of conditions where a routine systemic corticosteroid therapy is indicated. Its weaker sodium-retaining action usually makes it more suitable than cortisone in such conditions as rheumatoid arthritis, rheumatic fever, status asthmaticus and ulcerative colitis.

Posology and method of administration

For Oral use

Adults : Oral, 5 to 60 mg a day as a single dose or in divided dose, not exceeding 250 mg daily.

Children : As directed by physician.

Note : The pediatric dosage is determined more by the severity of the condition and response of the patient than by age or body weight.

The information given here is limited. For further information consult your doctor or pharmacist.

4.2 Contraindications

- Use is not recommended in nursing mothers, wherever possible.

4.4 Special warning and precautions for use

- Caution in patients with osteoporosis, peptic ulcer, psychoses, systemic fungal infections, diabetes mellitus, hypertension,

myasthenia gravis, ocular herpes simplex, glaucoma, hypothyroidism, history of tuberculosis, renal and hepatic function impairment.

- When medication is to be discontinued, dosage should be reduced gradually. Abrupt cessation of prolonged therapy may produce acute adrenal insufficiency.
- Frequency monitoring of drug effect is required.
- Caution in receiving vaccinations, other immunizations and skin test.
- Children on prolonged therapy should be closely observed.
- Safety for use in pregnancy has not been established.

4.5 Interaction with other medicinal products and other forms of interactions

- Response to prednisolone may be reduced by co-administration of barbiturates, phenytoin or rifampicin.
- Effects of oral anticoagulants or salicylates may be decreased when used concurrently with prednisolone.
- Caution in patients receiving the following drug therapy:
  Alcohol, anti-inflammatory medications, cardiac glycosides, ephedrine, heparin, hypoglycaemics.

4.6 Pregnancy and lactation

Safety for use in pregnancy has not been established

4.7 Effects on ability to drive and use machine

Not applicable

4.8 Undesirable effects

None known.

4.9 Overdose

Clinical features :

Nausea and vomiting, hyperglycaemia, occasional gastrointestinal bleeding.

Treat overdosage by symptomatic measures.

5-Pharmacological Properties :

5.1 Pharmacodynamic properties

Prednisolone, a synthetic glucocorticoid, has both anti-inflammatory and immunosuppressant actions. It acts by inhibition of phagocytosis, leukocyte migration and capillary dilatation, and prevention or suppression of cell mediated (delayed hypersensitivity) immune reactions respectively.

5.2 Pharmacokinetic properties

It is readily absorbed orally, metabolised in the liver and excreted via the kidneys.

6-Pharmaceutical Particulars:

6.1 List of excipients

Povidone
Maize starch
Lactose monohydrate
Magnesium stearate
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

Descriptions of each packaging material for Prednisolone Tablet is as below:
Immediate Container/Packaging

Type
Push-through blister pack; Blister package consists of transparent PVC film laminate (structure from outer to inner side) with the backing of aluminium foil coated with heat seal lacquer on inner side

Rigid Polyvinylchloride (PVC) Film
Description Polyvinylchloride (PVC) Film
Appearance 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 agent on bright surface

Appearance: Bright surface/Matt surface each side

Secondary packing material:
The blisters are packed in a cardboard carton with patient information leaflet.

6.6 Special precautions for disposal

Not applicable

7-Registrant

Marketing Authorization Holder:

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

Production Site : Hovid Bhd.
Lot 56442, 7 ½ Miles Jalan Ipoh / Chemor,
31200 Chemor,
Perak.

8-Date of revision of the text :
April 2022

9-Dosimetry (If applicable) :
Not Applicable

10-Instruction for preparation of Radiopharmaceuticals (If applicable):
Not Applicable