1. Name of the medicinal product

ESTRADIOL VALEATE TABLETS 2 MG

2. Qualitative and Quantitative Composition

SR. NO.	NAME OF THE INGREDIENTS	PHARMACOPEIAL SPECIFICATION	LABLE CLAIM	OVERAGES %	QTY. / TABLET	PURPOSE
ACTIVE INGREDIENTS						
1.	Estradiol Valerate*	USP	2 mg	20.00%	2.400mg	API
INACTIVE INGREDIENTS						
2.	Anhydrous lactose	BP	-	0.00%	75.000mg	Diluent
3.	Maize starch	BP	-	0.00%	60.000mg	Diluent
4.	Demineral water	INHOUSE	-	0.00%	0.010ml	Vehicle
5.	Povidone	BP	-	0.00%	4.000mg	Binder
6.	Lauroyl macrogol glycerides	BP	-	0.00%	0.600mg	Disintegrant
7.	Magnesium stearate	BP	-	0.00%	2.000mg	Lubricant
8.	Purified talc	BP	-	0.00%	2.000mg	Glidant
9.	Colloidal silicon dioxide	USP	-	0.00%	4.000mg	Glidant
10.	Dichloromethane**	BP	-	0.00%	0.100ml	Solvent
11.	Isopropyl alcohol**	BP	-	0.00%	0.100ml	Solvent
12.	Hydroxy propyl methyl cellulose (E-15)	BP	-	0.00%	2.800mg	Polymer
13.	Purified talc	BP	-	0.00%	0.200mg	Polisher
14.	Titanium dioxide	BP	-	0.00%	1.200mg	Colour
15.	Polyethylene glycol (Macrogol) 6000	BP	-	0.00%	0.800mg	Plasticizer

3. Pharmaceutical form

Oral Tablet

4. Clinical particulars

4.1 Therapeutic indications

Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women.

4.2 Posology and method of administration

1 tablet Estradiol Tablet 2 mg taken daily after a meal.

4.3 Contraindications

Hypersensitivity; undiagnosed vag bleeding; thrombophloebitis or pregnancy. thromboembolic disorders; breast carcinoma except in selected patients being treated for metastatic disease; oestrogen-dependent tumor; porphyria;

4.4 Special warnings and precautions for use

Discontinue if thrombotic event, unexplained visual changes, or jaundice occurs, and at least 4 weeks before through 2 weeks after surgery associated with increased risk of thromboembolism. Diabetes. Prediabetes. Depression. Uncontrolled dyslipidemias. Pregnancy-related cholestasis. Evaluate significant changes in headaches, irregular uterine bleeding, amenorrhea.

4.5 Interaction with other medicinal products and other forms of interaction

CYP1A2 and CYP3A4 inducers e.g. aminoglutethimide, carbamazepine, phenobarbital, and rifampin may decrease the effects of estradiol. May enhance the effects of hydrocortisone and prednisolone when used together.

4.6 Pregnancy and lactation

Pregnancy
Estradiol validates is not indicated during pregnancy. If pregnancy occurs during medication with Estradiol valerate, treatment should be withdrawn immediately.
The results of most epidemiological studies to date relevant to inadvertent fetal exposure to oestrogens indicate no teratogenic or foetotoxic effects.
Lactation
Estradiol valerateis not indicated during lactation.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

GI disturbances, genitourinary changes, haematologic disorders, CV and CNS effects, endocrine and metabolic disorders, cholestatic jaundice, local skin reactions, chorea, contact lens intolerance, steeping of corneal curvature, pulmonary thromboembolism, carbohydrate intolerance.

4.9 Overdose

Nausea and vomiting may occur with an overdose.
There are no specific antidotes, and treatment should be symptomatic. Withdrawal bleeding may occur in females with a uterus.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, natural and semisynthetic oestrogens, plain.
ATC code: G03CA03.
Estradiol is a naturally occurring oestrogen. Oestrogens are responsible for the development and maintenance of the female reproductive system and secondary sexual characteristics. They modulate the pituitary secretion of gonadotrophins, LH and FSH through a negative feedback system.

5.2 Pharmacokinetic properties

Absorption: Readily absorbed from the GI tract and through the skin or mucous membranes.
Distribution: Largely bound to plasma proteins.

Metabolism: Partly metabolised hepatically to less active oestrogens such as estriol and estrone.

5.3 Preclinical safety data

There are no preclinical safety data which could be of relevance to the prescriber and which are not already included in other relevant sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

- Anhydrous lactose
- Maize starch
- Demineral water
- Povidone
- Lauroylmacrogolglycerides
- Magnesium stearate
- Purified talc
- Colloidal silicon dioxide
- Dichloromethane
- Isopropyl alcohol
- Hydroxy propyl methyl cellulose (E-15)
- Titanium dioxide
- Polyethylene glycol (Macrogol) 6000.

6.2 Incompatibilities

Not known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C and Protect from light.

6.5 Nature and contents of container

10 x 1 x 28 tablets Alu – PVC Blister pack , packed in printed and laminated carton

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

West Coast Pharmaceutical Works Ltd, Ahmedabad

8. Marketing authorisation number(s)

Not applicable.

9. Date of first authorisation/renewal of the authorisation

Not applicable.

10. Date of revision of the text

May 2020