

Safety data sheet

Activella® 1.0 mg/0.5 mg, Activella 0.5 mg/0.1mg

1. Identification of the substance/preparation and of the company/undertaking

Prepared on: 08-04-2013/ FRSE

Product use: Hormone Replacement Therapy

Distributor:

Novo Nordisk A/S

External Environment

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2. Hazards identification

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The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.

CLP-classification

Carc. 2; Repr. 1A; Lact.;

H351; H360Fd; H362

Suspected of causing cancer. May damage fertility. Suspected of damaging the unborn child. May cause harm to breast-fed children.

Additional information

Activella is a continuous combined hormone replacement product intended for use in women with an intact uterus.

3. Composition/information on ingredients

REACH registration number	CAS No./ EINECS no.	Substances	Classification/ CLP-classification	w/w%
-	50-28-2	0.5 mg Estradiol and 0.1 mg	T; R60, Xn; R40, R63, R64	0,5-1
	51-98-9	Norethisterone acetate (active ingredient)	Carc. 2; H351, Repr. 1A; H360Fd Lact. H362	.
	.	1 mg Estradiol and 0.5 mg	-	.
	.	Norethisterone acetate (active ingredient)	Carc. 2; H351	0,5-1

Please see section 16 for the full text of R-phrases and H-phrases.

4. First aid measures

Inhalation

Remove to fresh air. If breathing is irregular, call a physician immediately.

Ingestion

Rinse mouth thoroughly and then drink plenty of water. Do not induce vomiting. Seek medical advice in case of persistent discomfort.

Skin

Wash with soap and water. Seek medical attention if irritation develops.

Eyes

Flush eyes with water for 15 minutes. If irritation develops, seek medical attention.

Other information

If in doubt, contact the doctor or emergency room. Always carry this manual or label.

5. Fire-fighting measures

The product is not readily flammable. Avoid breathing vapors and flue gases - seek fresh air.

Fire Fighting Extinguishing Media: In case of fire use foam, waterspray, dry chemical or CO₂.

6. Accidental release measures

Use the same personal protective equipment as stated in section 8. Mop up spillage with a cloth. Dam spill and collect with sand or other absorbent material and place in suitable waste containers. For information on disposal please see item 13.

7. Handling and storage

Handling

See section 8 for information about precautions for use and personal protective equipment.

Storage

Do not store above 25°C. Do not refrigerate. Keep the container in the outer carton in order to protect from light.

8. Exposure controls/ personal protection

Precautions for use

Work under effective process ventilation (e.g. local exhaust ventilation).

There must be access to running water and eye wash.

Respiratory protection

Not normally required. But if the tablets crushed and dust is released personal protection (breathing protection (filtertype P3) must be used.

Gloves and protective clothing

Nitril rubber or similar of greater protection are recommended for waste clean-up and manufacturing and packaging operations.

Eye protection

Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a risk of splashing.

Occupational exposure limits

Contains no substances subject to reporting requirements.

9. Physical and chemical properties

Appearance: White film coated, round tablet

Solubility in water: Insoluble

Melting point: 173-179 °C

10. Stability and reactivity

No known incompatibilities. No known hazardous decomposition products.

11. Toxicological information

Acute

Inhalation

Not investigated. May be harmful if inhaled. May cause respiratory tract irritation.
Activella® tablets contain very potent steroid that can be absorbed by the inhalation as well as orally.

Ingestion

Activella® tablets are intended for oral administration. Accidentally systemic exposure to steroid hormones may cause serious effects including cancer dependent on the duration and frequency of exposure.

Skin contact

May be harmful if absorbed through skin. May cause skin irritation. Avoid contact with the skin.

Eye contact

May cause irritation. Avoid contact with the eyes.

Long-term effects

Activella® tablets contain potent steroidal estrogens, which are known according to the International Agency for Research on Cancer (IARC).

Cancer

To cause an increased risk of breast cancer in women.

May cause damage to the reproductive system

Suspected human reproductive toxicant. Damage to fetus cannot be excluded.
Effects on or via lactation may damage fertility. Suspected of damaging the unborn child.

12. Ecological information

Do not discharge large quantities of concentrated spills and residue into drains.

13. Disposal considerations

The product is not hazardous waste .
It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications.
Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

14. Transport information

The product is not covered by the rules for the transport of dangerous goods by road and sea according to ADR and IMDG.

15. Regulatory information

Hazard designation: It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

Signal word: Danger

Contains

0.5 mg Estradiol and 0.1 mg Norethisterone acetate (active ingredient),
1 mg Estradiol and 0.5 mg Norethisterone acetate (active ingredient)

Supplemental information

None.

Chemical safety assessment

Chemical safety assessment has not been performed.

16. Other information

Restrictions on use

None.

Training requirement

No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Sources used

Other information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

Full text of the R-phrases that are stated in section 3.

R40 Limited evidence of a carcinogenic effect.

R60 May impair fertility.

R63 Possible risk of harm to the unborn child.

R64 May cause harm to breast-fed babies.

Full text of the H-phrases that are stated in section 3.

H351 Suspected of causing cancer.

H360Fd May damage fertility. Suspected of damaging the unborn child.

H362 May cause harm to breast-fed children.

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