Safety data sheet

Norditropin® FlexPro® 5 mg/1.5 ml
Norditropin® FlexPro® 10 mg/1.5 ml
Norditropin® FlexPro® 15 mg/1.5 ml
Norditropin® NordiFlex® 30 mg/3.0 ml

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

Revision: 03-12-2012/ FRSE
Replaces: 13-09-2010

Product use: This product is a growth hormone. For information on indications please see instruction for use.

Distributor:
Novo Nordisk A/S
External Environment
Novo Allé DK-2880 Bagsværd

Tel:+45 44 44 88 88 Fax:+45 44 49 05 55
Emergency telephone +45 44 42 00 00
Email adresse: compliance-team@novonordisk.com

2. Hazards identification

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

Additional information
Norditrpin® is a drug product and should be used in accordance with the instructions for use. The product is tested according to applicable regulations for pharmaceutical products.

3. Composition/information on ingredients

REACH registration number	CAS No./ Einecs no.	Substances	Classification/ CLP-classification	w/w%	
-	12629-01-5	Aqueous solution for injection containing somatropin	Not classified	-	-

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

4. First aid measures

Inhalation
Seek fresh air. Seek medical advice in case of persistent discomfort.

Ingestion
Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.

Skin
Remove contaminated clothing. Wash the skin thoroughly with water and continue washing for a long time. Seek medical advice in case of persistent discomfort.

Eyes
Flush immediately with water (preferably using eye wash equipment) for at least 5 minutes. Open eye wide. Remove any contact lenses. Seek medical advice.

Other information
When obtaining medical advice, show the safety data sheet 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 protection as listed 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
Norditropin® FlexPro® should be stored in a refrigerator between 36 ° F to 46 °F (2 °C to 8 °C). Do not freeze Norditropin® FlexPro® and do not use if it has been frozen. Norditropin® FlexPro® must not be exposed to heat or direct light. Store according to product instruction to prevent degradation.

8. Exposure controls/ personal protection

Precautions for use
There must be access to running water and eye wash.

Respiratory protection
Not required.

Gloves and protective clothing
Wear disposable gloves made of nitrile rubber (NBR).

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: Clear, colourless liquid
Odor: Smell of phenol
Boiling point: 100 °C
Relative density: 1.01 g/cm ³ at 25 °C

Molecular formula: C990H1528N262O300S7
Molecular weight: 22125 Da

10. Stability and reactivity

The product is stable when used and stored in accordance with instruction for use.

11. Toxicological information

Acute

Inhalation
Not investigated. Inhalation of sprit mist containing protein may cause sensitization.

Ingestion
Not investigated. Ingestion may cause discomfort.

Skin contact
May cause irritation by the active substance or any of the excipients. Avoid contact with the skin.

Eye contact
May be temporary irriating. Avoid contact with the eyes.

Risk of sensitization
Hypersensitivity to the active substance or to any of the excipients, Norditropin® contains phenol which may cause allergic reactions.

Long-term effects
Repeated dose studies in animals did not identify any target organ toxicity.

12. Ecological information

Do not discharge spills and residue into drains.

13. Disposal considerations

The product is not hazardous waste under the Waste Decree.
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 regulated as of dangerous goods 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.

Contains
Norditropin® FlexPro® 5mg/1.5 ml, item number 5-2050-10
Norditropin® FlexPro® 10 mg/1.5 ml, item number 5-2051-00
Norditropin® FlexPro® 15mg/1.5 ml, item number 5-2052-00
Norditropin® Nordiflex® 30mg/3 ml, item number 5-20523-00

Supplemental information
None.

Chemical safety assessment

16. Other information

Restrictions on use
None.

Training requirement
No special training is necessary but instructions for use should be followed.

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.
No R-phrases.

Full text of the H-phrases that are stated in section 3.
No H-phrases.