

Gemsol, Gemcitabin Ebewe 40 mg /ml Safety Data Sheet

According to REACH Directive (EU) No. 1907/2006



EBEWE ONCOLOGY
Oncology Injectables by Sandoz

Safety-Data-Sheet

According to REACH Directive (EU) No. 1907/2006

Brand name: Gemcitabine Ebewe - Gemsol
Last modification: June 2010 version: 1

This safety data sheet refers to the finished pharmaceutical product

1. Product and Company Identification

Brand name: Gemcitabine Ebewe (Gemsol)

Active ingredient: Gemcitabine hydrochloride

Chemical name: 2'-Desoxy-2',2'-difluoro-Cytidin-Hydrochloride

Formula: $C_5H_{11}O_4N_3F_2 \text{ HCl}$

Pharmacotherapeutic category:

Antineoplastic agent for treating cancer

Manufacturer and Marketing Authorisation Holder:

EBEWE Pharma Ges.m.b.H.Nfg

Mondseestr. 11

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Austria

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In cases of emergency: +43 664 30 83 234

2. Potential hazards

Hazard designation:

Cytotoxic agent

Classification system:

Pharmaceuticals, which are subject to an approval procedure or registration process in keeping with the pharmacopoeia, are exempt from the provisions of the Chemicals Act.

- Toxic by inhalation, if swallowed and after contact with skin
- may cause hereditary damage
- can affect fertility
- may irritate the respiratory organs and the skin.
- may cause serious eye damage

3. Composition

	Symbol	R-phrases	Concentration per ml
Gemcitabine hydrochloride	T: toxic	R 40, R 62, R 63, R 24, R 36/38	40 mg/ml

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4. First-aid measures

After skin contact:

- Wash with copious amounts of soap and water.
- Immediately remove any contaminated clothing and dispose of safely (hazardous waste).
- Seek medical advice

After eye contact:

- Remove contact lenses.
- Immediately rinse eyes with plenty of water for fifteen minutes
- Seek medical advice

After swallowing:

- Rinse the mouth with water
- Do not induce vomiting
- Seek medical advice

5. Fire-fighting measures

Suitable fire-extinguishing agents:

- Directed water jet.
- Dry extinguishing powder.
- Carbon dioxide.
- Foam extinguisher
- Halones

Unsuitable fire-extinguishing agents:

Full water jet.

Special hazards caused by the agent, its combustion product or gases produced:

The development of carbon dioxide, nitrous gases and other chemical compounds with cancerogenous potential is possible.

Special protective equipment for fire fighting:

Wear breathing apparatus independent of the ambient air and don protective clothing.

6. Measures in case of unintentional release

Personal precautionary measures:

In case of spills:

- evacuate the area - keep unprotected persons away
- avoid inhalation and contact with skin and eyes
- wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area

Environmental protection measures:

- the product or contaminated firewater must not get into the sewage system / upper water / ground-water.

Method of cleaning

- Soak up any spilled fluid with copious amounts of cotton wool or similar
- soil: collect carefully and place in a closable container
- thoroughly clean the affected area after complete removal of the material
- dispose all materials used in the cleaning process including the personal protection equipment as hazardous waste

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7. Handling and storage

Notes on safe handling:

- Take appropriate measures to prevent any contact with skin or inhalation of aerosols
- Only open and withdraw fluid from vials or ampoules in safety cabinets for cytotoxic handling or isolators
- wear personal protective clothing (gloves designated for handling cytotoxic drugs)
- ensure correct and clean method of working
- Do not keep, eat or drink any food or beverages in the work area.

Notes on protection against fire and explosion:

- In case of a fire in the vicinity, protect the product against heat or cool the container.

Requirements on storage areas and containers:

- Store in original primary packaging only.
- Store separated from food
- Do not store together with lyes
- Do not store together with acids
- Do not store together with oxidizing agents

Further information on storage conditions: Please refer to the local SPC and PIL.

8. Exposure limitation and personal protection equipment

- Use suitable safety cabinets or isolators for preparation – please refer to your local regulations and laws.
According to the ISOPP Standards of Practice of 2007 biological safety cabinets (BSC) of at least class 2 (EN 12469 2000) which are designed and constructed for the preparation of sterile products should be used.
- Keep the development of aerosols to a minimum via correct working technique.
- Provide emergency shower.
- Provide eye bath.

Limitation of exposure:

Due to the absence of conclusive scientific examinations so far, it is still not possible to define work protection values (TLV values, PEL values, TRC values) for finished cytotoxic pharmaceuticals.

Personal protection equipment:

General protection and hygiene measures

- Do not eat, drink or smoke during work
- Avoid contact with skin, eyes and mucous membranes
- Immediately change contaminated, saturated clothing; only wear again after cleaning
- Wear fresh clothing every day
- Do not wear used work clothing outside of the working area.
- Use water and soap to thoroughly wash hands before breaks and after work
- The product must be handled by trained personnel only

Breathing protection

- no special protection is necessary when the product is handled inside a safety cabinet or an isolator
- use filter type with filter class P3 when cleaning up spills

Protective clothing

- Wear protective gloves designated for handling of cytotoxics, e.g. made of latex (wearing duration - 20 minutes maximum).
- Protect exposed skin (e.g. gown, safety goggles if applicable)

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9. Physical and chemical characteristics

Appearance: clear, colorless or almost colorless solution
pH: 2.0 – 2.8
Density: 1.016 g/ml

10. Stability and reactivity

Stability: Stable under recommended storage conditions.
Materials / conditions to be avoided: None known

11. Information on toxicology

Cytotoxic substance; cancerogenic, mutagenic and teratogenic properties.
For further information please refer to the local SPC and PIL

12. Environment-related information

General instructions:

This product must not be released into the environment.

Water hazard classification (WHC):

The substance potentially constitutes a water hazard and must not get into the sewage system undiluted.

13. Information on disposal

Waste must be segregated, packaged, and disposed of in a way that personnel and the environment are not contaminated according to local regulatory laws and regulations for cytotoxic drugs.

14. Information on transport

Transportation must be in accordance with all local, state, provincial or federal legislation concerning the transport of hazardous agents.

Note: Final pharmaceutical products are no hazardous freight in keeping with the ADR/GGVSE (special regulation 601) applicable for road and rail traffic.

UN-No.: UN 1851
ADR/GGVSE-Class: 6.1
Name: Drug, liquid, toxic, no further remarks

IATA: NF
IMDG: NF
ADR: NF
RID: NF
ADNR: NF

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15. Legal regulations

The final pharmaceutical product is not subject to labeling requirement according to EU guidelines.

16. Miscellaneous information

Miscellaneous notes:

These data describe the safety requirements of the product exclusively and are based on today's state of knowledge. They are no assurance of characteristic features of the product described in the sense of the legal warranty provisions.

The safety data sheet is used to describe the product with respect to handling and safety requirements.

For more information please refer to the local SPC and PIL.