PRODUCT SPECIFICATION FOR DEXELL

Product Importing Application Form

1-Product Information

Product (Trade) name (as used in the country of origin) **DEXELL VUR**

Active Substance (s):	Hyaluronic Acid Sodium Salt & Dextranomer

form:	Implantation

Route of Administration:	93/42/EEC Medical Device Directive

Container. closure and administrative device (s):	Syringe

Pack sizes and strengths used in the country of origin:	20.5cm*2.3cm*2.3cm

Shelf Life period:	36 Month
Shelf lifer (after first opening container):	Single Use only

Storage conditions :	2-25 C

2- Manufacturer

Marketing Authorization Holder (Name Address & Country):	SZUTEST, 2195 (YUKARI DUDULLU MH. NATO YOLU CD. ÇAM SK. N0:7ÜMRANIYE - İSTANBUL /TURKEY TEL: +90 216 4694666 (PBX) FAX: +90 216 4694667)
Number and Date of the first Marketing Authorization / Renewal	11.09.2009
Manufacturer of Finished Product (Name Address & Country):	İSTEM MEDİKAL TIBBİ CİHAZ VE SAN. TİC. LTD. ŞTİ. İVEDİK ORGANİZE SAN. BÖLGESİ 661.Sok.Altınarı Yapı Koop. No:4 OSTİM-ANKARA/TURKEY
License Holder of Finished product (Name , Address & Country):	İSTEM MEDİKAL TIBBİ CİHAZ VE SAN. TİC. LTD. ŞTİ. İVEDİK ORGANİZE SAN. BÖLGESİ 661.Sok.Altınarı Yapı Koop. No:4 OSTİM-ANKARA/TURKEY

List the active substance(s) and the excipient (s)

Components	Formula	IUPAC	Function	Qty (mg)	Unit	Reference
Hyaluronic Acid Sodium Salt	(C14H20N NaO11)n	Sodium hyaluronate,	serves as vehicle for the Dextranomer - microparticles.	17	mg	Ph.Eur. 1472**.**
DEAE Shephadex A-25		Dextranomere	microparticles stimulate the connective tissue ar the locality of injection.	50	mg	According to GE specification

3- Hazards identification

Hazard designation
n/a

4- First – aid measures

Inhalation:N/A
Skin contact: N/A
Eye contact: N/A
Ingestion:N/A

5- Fire – fighting measures

Suitable extinguishing media: N/A
Unsuitable extinguishing media:N/A
Additional information:N/A

6- Accidental release measures

Personal precautions
Check integrity of package and blister pack before application.
If package and blister pack are damaged, the product must not be used.
Store at 2° to 25°C .
For expiry date (exp.date) see package and blister pack. DEXELL VUR must not be used after the given date.
Keep out of the reach of children.

Note:

The scalling on the syringe is only an orientation for the user, related to the final volume. It is not a measurement function. It only shows the amount used related to nominal volume of 1 ml.

Environmental precautions N/A

7- Handling and storage

Information for safe handling
Check integrity of package and blister pack before application.
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Information about protection against explosions and fires N/A

Further information about storage conditions
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8- Exposure controls and personal protection

Components with critical values that require monitoring at the workplace (exposure limits) No specific data

Personal protective equipment
General protective and hygiene measures
No known significant effects or critical hazard .No action shall be taken involving any personal risk or without suitable training

Respiratory protection: No known significant effects or critical hazard. If inhaled, remove fresh air, Get medical attention if irritation develop

Hand protection: No known significant effects or critical hazard .Wash with soap and water. Get medical attention if irritation develop

Eye Protection: No known significant effects or critical hazard. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if irritation develop

Body Protection: No action shall be taken involving any personal risk or without suitable training

9- Physical and chemical properties Image + Reference + COA

Form :Clear lightly opalescent solution free of visible particle
Colour : Colorless
Odour: Odorless

Relevant safety date:N/A
Boiling point / rang:N/A
Vapor pressure :N/A
Densing:N/A
Solvent – sparation test:N/A
Solubility in water: Insoluble
PH Value:7.3-7.8
Flow Time:N/A
Viscosity: 39.000-51.000m PAS

10- Stability and reactivity The product is stable

Conditions to avoid :No Specific Data

Materials to avoid :No Specific Data

11- Toxicological information

Toxicological test
LD50/LC50 values that are relevant for classification: N/A

12- Ecological information

Details on elimination (Persistence / degradability): N/A

Additional ecological information N/A
Additional ecological data N/A
Specification :
Value / dosage :1 ml

13- Disposal considerations

Dispose as per local, state or federal regulation.

14- Side effect(s) :

Caused by the injection: As with any other injection, patients may suffer from the following symptoms:
_ temporary erythema
_ slight swelling
_ pain
_ itching
_ discolouration
_ hardening
Typically these reactions spontaneously disappear within 2 to 5 days following the injection.

Caused by the product: A hypersensitivity to hyaluronic acid following the injection has been reported less than 1 % out of 5000 treatments. This hypersensitivity is shown through an extended erythema, swelling and hardening at the implantation site. These reactions can occur immediately after the injection or up to 2 to 4 weeks later. Clinical data proves that these reactions are mild to moderate and last for a maximum of two weeks. These reactions can be caused through the endotoxins remaining in the hyaluronic acid solution (0.025 I.U./mg). This is the highest level of purity that hyaluronic acid products can have. The specially manufactured dextranomers are biologically degradable but can in rare cases result in a formation of granuloma, which can be decomposed using the corresponding therapy (enzymes). Patients with multiple allergies should therefore be excluded from treatment.

15- Regulatory information

Classification according to EEC directives-CLASS III
Danger symbol and danger designation: No Danger

Hazard – determining components of labeling: Single Use Only, Sterile,

Risk – Phrases

All appearing risks that can generally occur during the application of the products of our product group have been evaluated and accepted accordingly. No further risks were induced by the taken measures. Basics for the assessment:- The assumed user's state of knowledge correspond to that of specialized surgeons.- The product status: new products.Result: The benefits of product clearly outbalance the possible risks.

Safety – Phrases:
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National regulatory information N/A
Regulation on inflammable liquids N/A
Emission control act N/A
Water pollution classification N/A

16-Transport Information

UN No: N/A
Proper Shipping Name: N/A
Air Transport (ICAO & IATA): Harmless
Class: N/A
Packaging Group: N/A

17- Other information

Further information
R- phrases of components: Indicates information that has changed from previously issued version.

This is to certify that the information contained herein is true and correct.
Name and title of responsible official in the company :İSTEM MEDİKAL
Signature of responsible official in the company :Levent HAYYAOĞLU
Date and Stamp :
Full Address :Ivedik. Organize San. Böl. 661.Sok. No:4 Ostim-ANKARA/TURKEY

SIGNATURE & DATE

Levent HAYYAOĞLU 04.09.2015