



PRODUCT LIST

SHENZHEN MELLOW HOPE PHARM INDUSTRIAL CO., LTD.



Human Vaccines

- Freeze-dried Live Attenuated **Hepatitis A** Vaccine (H2 strain)
- Recombinant **Hepatitis E** Vaccine (Escherichia Coli)
- **Varicella** Vaccine (Live), Freeze-dried
- **Rabies** Vaccine for Human Use (Vero cell), Freeze-dried
- **Meningococcal** Polysaccharide Vaccine (Group A/C/Y/W₁₃₅)
- **Meningococcal** Conjugated Vaccine (Group A/C/Y/W₁₃₅)
- **Meningococcal** Group A and C Conjugate Vaccine
- Recombinant Human **Papillomavirus Bivalent** (Types 16,18) Vaccine (Escherichia coli)
- Recombinant Human **Papillomavirus 9-Valent** Vaccine (E. Coli)
- **Trivalent Influenza** Vaccine (Split Virion), Inactivated
- Inactivated **Poliomyelitis** Vaccine
- **13-Valent Pneumococcal** Polysaccharide Conjugate Vaccine
- **Enterovirus** Type 71 Vaccine, Inactivated (Human Diploid Cell) (EV71)

Rabies Vaccine for Human Use (Vero cell), Freeze-dried

English Name: Rabies Vaccine for Human Use (Vero Cell), Freeze-dried

Dosage Form: Freeze-dried powder for injection

Strain: This product is prepared by inoculating Vero cells with the fixed rabies virus strain CTN-1V ; the potency of the rabies vaccine shall be not less than 2.5 IU.

Specification(Dosage): 0.5 ml/dose per vial.

Indication: Prevention against rabies virus.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: Verorab® / Rabivax®

Manufacturer: Sanofi Pasteur / Bio Farma

Varicella Vaccine (Live), Freeze-dried

English Name: Varicella Vaccine (Live), Freeze-dried

Dosage Form: Freeze-dried powder for injection

Strain: The WHO-recommended human diploid cell line MRC-5 is selected as the production cell substrate, and the WHO-recommended Oka strain of varicella virus is selected as the production virus strain.

Specification(Dosage): 0.5ml/dose per pre-filled syringe

Indication: Prevention against varicella among subjects aged more than 12 months.

Administration: Subcutaneous injection



ORIGINATOR INFORMATION

Brand Name: Varivax® / Varilrix®

Manufacturer: Merck & Co., Inc. / GlaxoSmithKline (GSK)

13-Valent Pneumococcal Polysaccharide Conjugate Vaccine

English name: 13-Valent Pneumococcal Polysaccharide Conjugate Vaccine

Dosage form: Suspension for injection

Strain: Pneumococcus serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F are used as the bacterial strains for vaccine production.

Specification(Dosage): 0.5 ml/dose per pre-filled syringe.

Indication: Protect infants over 2 months, young children, and adults against disease caused by the bacterium *Streptococcus pneumoniae*.

Administration: Intramuscular injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Prevnar 13®

Manufacturer: Pfizer Inc.

Influenza Vaccine (Split Virion), Inactivated, Trivalent

English Name: Influenza Vaccine (Split Virion),
Inactivated, Trivalent

Dosage Form: Solution for Injection

Strain: Northern/Southern Hemisphere virus
strains recommended by WHO are used for
vaccine production.

Specification(Dosage): 0.25ml/0.5ml/dose per pre-
filled syringe or vial.

Indication: It is indicated for prevention against
influenza viruses of prevalent strains.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: Vaxigrip® / Influvac® / Fluzone®

Manufacturer: Sanofi Pasteur / Abbott / Seqirus

Recombinant Human Papillomavirus Bivalent (Type 16, 18) Vaccine (Escherichia coli)



English Name: Recombinant Human Papillomavirus Bivalent (Type 16, 18) Vaccine (Escherichia coli)

Dosage Form: Liquid for injection

Strain: Papillomavirus type 16, 18 are used as the virus strains for vaccine production; each dose contains: 40µg recombinant HPV 16 L1 protein and 20µg HPV 18 L1 protein.

Specification(Dosage): 0.5 ml/dose per vial.

Indication: Indicated for women aged 9-45 years to prevent Cervical cancer, Cervical intraepithelial neoplasia Grade 1, Grade 2 or 3 (CIN2/3), adenocarcinoma in-situ (AIS) and persistent infections of HPV types 16 and/or 18.

Administration: Intramuscular injection

WHO Pre-qualification: Yes

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Cervarix®

Manufacturer: GlaxoSmithKline Biologicals

Meningococcal Group A and C Conjugate Vaccine

English Name: Meningococcal Group A and C Conjugate Vaccine

Dosage Form: Freeze-dried Powder for Injection

Strain: Neisseria meningitidis serogroup A and serogroup C are used as the bacterial strains for vaccine production.

Specification(Dosage): 0.5 ml/dose per vial.

Indication: It is indicated for prevention against diseases caused by Meningococcal Group A, C, such as cerebrospinal meningitis and septicemia (general infection) for Infants and children at the age of 3 months to 5 years.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: Menjugate® / MenAC®

Manufacturer: GlaxoSmithKline Biologicals

Group ACYW₁₃₅ Meningococcal Polysaccharide Vaccine

English Name: Group ACYW₁₃₅ Meningococcal Polysaccharide Vaccine

Dosage Form: Freeze-dried Powder for Injection

Strain: Neisseria meningitidis serogroups A, C, Y, and W₁₃₅ are used as the bacterial strains for vaccine production.

Specification(Dosage): 0.5 ml/dose per vial.

Indication: The vaccine is indicated for active immunization of adults and children over two years old.

Administration: Subcutaneously injection



ORIGINATOR INFORMATION

Brand Name: Menactra® / Menveo®

Manufacturer: Sanofi Pasteur / GlaxoSmithKline

Group ACYW₁₃₅ Meningococcal Conjugate Vaccine (CRM197)

English Name: Group ACYW₁₃₅ Meningococcal Conjugate Vaccine (CRM197)

Dosage Form: Freeze-dried powder(Group A, C) + Solution (Group Y, W₁₃₅) for Injection

Strain: Neisseria meningitidis serogroups A, C, Y, and W₁₃₅ are used as the bacterial strains for vaccine production.

Specification(Dosage): 0.5 ml/dose per vial

Indication: Protect children aged 3 months to 3 years against the ongoing threat of meningitis.

Administration: Intramuscular Injection



ORIGINATOR INFORMATION

Brand Name: MenQuadfi®

Manufacturer: Sanofi Pasteur

Freeze-dried Live Attenuated Hepatitis A Vaccine (H2 strain)

English Name: Hepatitis A (Live) Vaccine, Freeze-dried

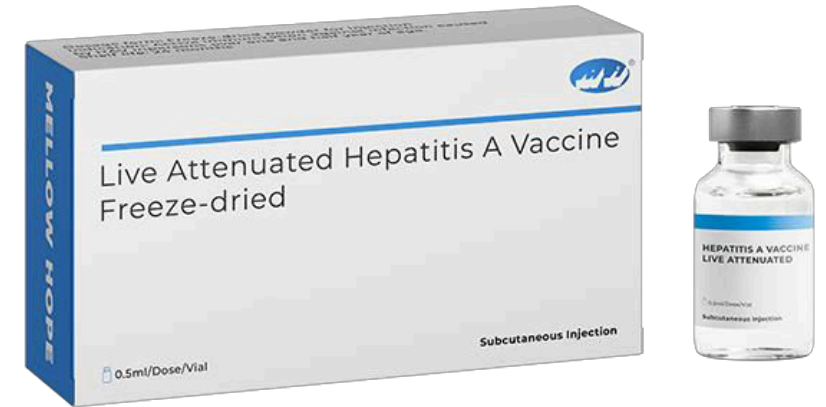
Dosage Form: Freeze-dried powder for injection

Strain: Prepared by inoculating human diploid cells with an attenuated strain of hepatitis A virus.

Specification(Dosage): 0.5 ml/dose per vial

Indication: Active immunization against infection caused by HAV in persons over one and half year of age.

Administration: Subcutaneous injection



ORIGINATOR INFORMATION

Brand Name: /

Manufacturer: /

Recombinant Hepatitis E Vaccine (Escherichia Coli)

English Name: Hepatitis E Vaccine (E. coli)

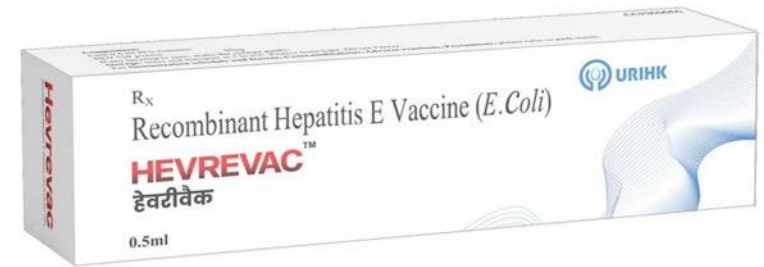
Dosage Form: Liquid for injection

Strain: Prepared using recombinant Escherichia coli engineered with the hepatitis E virus strain.

Specification(Dosage): 0.5ml/dose per pre-filled syringe

Indication: Prevention against hepatitis E for susceptible population aged 16 years and above.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: /

Manufacturer: /

Recombinant Human Papillomavirus 9-Valent Vaccine (E. Coli)

English Name: Recombinant Human Papillomavirus 9-Valent Vaccine (E. Coli)

Dosage Form: Suspension for injection

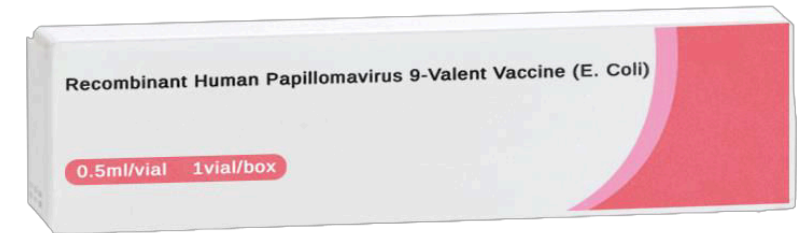
Strain: Papillomavirus type 6, 11, 16, 18, 31, 33, 45, 52, and 58 are used as the virus strains for vaccine production.

Specification(Dosage): 0.5 ml/dose per vial or pre-filled syringe

Indication: Protect individuals ages 9 to 45 against the following diseases caused by 9 types of HPV (6, 11, 16, 18, 31, 33, 45, 52, and 58) : cervical, vaginal, and vulvar cancers in females, anal cancer, certain head and neck cancers, such as throat and back of mouth cancers and genital warts in both males and females.

Administration: Intramuscular injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Gardasil 9®

Manufacturer: Merck & Co., Inc.

Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains

English Name: Poliomyelitis Vaccine (Vero Cell),
Inactivated, Sabin Strains

Dosage Form: Liquid for injection

Strain: Attenuated Sabin poliovirus strains type I, II,
and III are used; 0.5ml for per person every time;
containing the amount of antigen for poliovirus type
I 30DU, type II 32DU, type III 45DU.

Specification(Dosage): 0.5 ml/dose, 10 doses per vial;

Indication: active immunization for infants and
children aged ≥ 2 months against poliomyelitis.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: IPOL® / Poliovac®

Manufacturer: Sanofi Pasteur / Sinovac

Enterovirus Type 71 Vaccine, Inactivated (Human Diploid Cell) (EV71)

English Name: Enterovirus Type 71 Vaccine, Inactivated (Human Diploid Cell) (EV71)

Dosage Form: Suspension for injection

Strain: Inoculated African green monkey kidney cells (Vero cells) with Enterovirus 71 (EV71 H07 strain).

Specification: 0.5mL/dose per vial.

Indication: Indicated for active immunization to prevent hand, foot, and mouth disease caused by Enterovirus 71 in children aged 6 months to 5 years.

Administration: Intramuscular injection



ORIGINATOR INFORMATION

Brand Name: /

Manufacturer: /



Bio-pharmaceuticals

Insulin & GLP-1 Products

- Insulin [Glargine](#) Injection
- Insulin [Aspart](#) Injection
- [Liraglutide](#) Injection

Plasma Products

- Human Immunoglobulin for Intravenous Injection (pH4) ([IVIG](#))
- Human [Coagulation Factor VIII](#)
- Human [Hepatitis B](#) Immunoglobulin
- Human [Tetanus](#) Immunoglobulin
- Human [Rabies](#) Immunoglobulin Injection (HRIG)

MABs Products

- [Adalimumab](#) Injection
- [Bevacizumab](#) Injection
- [Trastuzumab](#) Injection
- [Tocilizumab](#) Injection
- [Pertuzumab](#) Injection

In Pipeline:

- [Denosumab](#) Injection
- [Rituximab](#) Injection

Growth Factors & Others

- Human [Growth Hormone](#) Injection
- Recombinant Human Basic Fibroblast Growth Factor for External Use ([rh-bFGF](#))
- Recombinant Human [Epidermal Growth Factor](#) Eye Drops
- Recombinant Human [Coagulation Factor VIII](#)
- [Levonorgestrel Silastic](#) Implants

Human Immunoglobulin (pH4) for Intravenous Injection

English Name: Human Immunoglobulin (pH4) for Intravenous Injection

Dosage Form: A colorless or pale yellow clear or slightly opalescent liquid

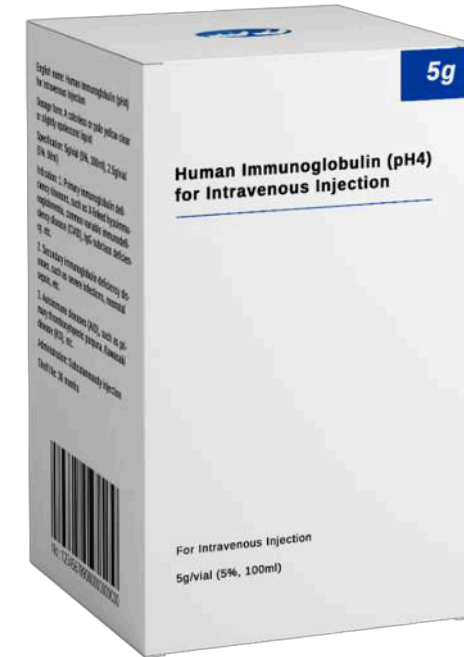
Specification(Dosage): 5g/vial (5%, 100ml), 2.5g/vial (5%, 50ml), (5g/vial 10%, 50ml, to be available soon).

Not available: 10g 5%, 6g 5%, 1.25g 5%, etc.

Indication: 1. Primary immunoglobulin deficiency diseases, such as X-linked hypogammaglobulinemia, common variable immunodeficiency disease (CVID), IgG subclass deficiency, etc. 2. Secondary immunoglobulin deficiency diseases, such as severe infections, neonatal sepsis, etc. 3. Autoimmune diseases (AID), such as primary thrombocytopenic purpura, Kawasaki disease (KD), etc.

Administration: Intravenous injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Privigen® / Octagam® / Flebogamma®

Manufacturer: CSL Behring / Octapharma / Grifols

Liraglutide Injection

English Name: Liraglutide Injection

Dosage Form: Solution for injection in pre-filled pen

Specification(Dosage): 18mg/3mL (disposable pen)

Indication: Indicated for type 2 diabetes mellitus.

Administration: Subcutaneous injection

Registration Category: Biological Drug

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Victoza® / Saxenda®

Manufacturer: Novo Nordisk A/S

Liraglutide (BF)

Adalimumab Injection

English Name: Adalimumab Injection

Dosage Form: Liquid for injection

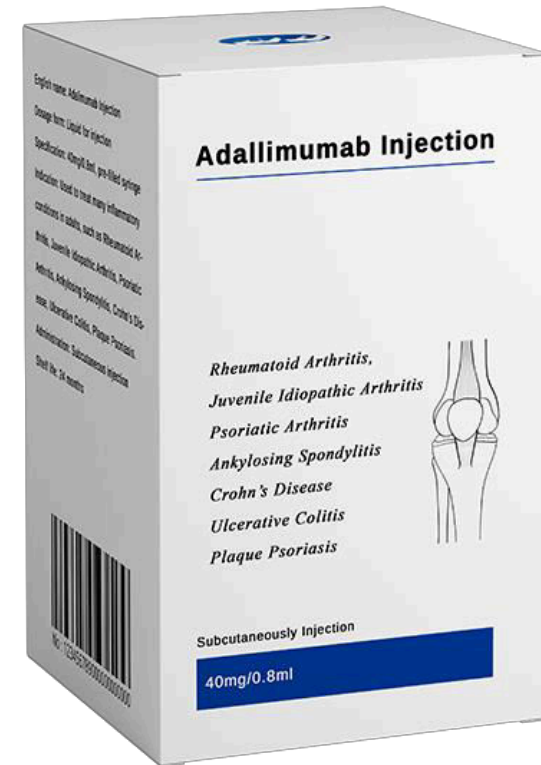
Specification(Dosage): 40mg/0.8ml; Vial or Pre-filled syringe

~~Not available: 80 mg/0.8 mL, 40mg/0.4 mL, 20mg/0.2 mL, 10mg/0.1 mL~~

Indication: Used to treat many inflammatory conditions in adults, such as Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis.

Administration: Subcutaneous injection

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Humira®

Manufacturer: AbbVie Inc.

Adalimumab

Bevacizumab Injection

English Name: Bevacizumab Injection

Dosage Form: Liquid for injection

Specification(Dosage): 100mg/vial; (400mg is still in pipeline)

Indication: Indicated for Metastatic Colorectal Cancer, Advanced, Metastatic, or recurrent Non-small-cell Lung Cancer.

Administration: Intravenous injection

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Avastin®

Manufacturer: Genentech, Inc. (a member of the Roche Group)

Bevacizumab

Trastuzumab Injection

English Name: Trastuzumab Injection

Dosage Form: Lyophilized powder for injection

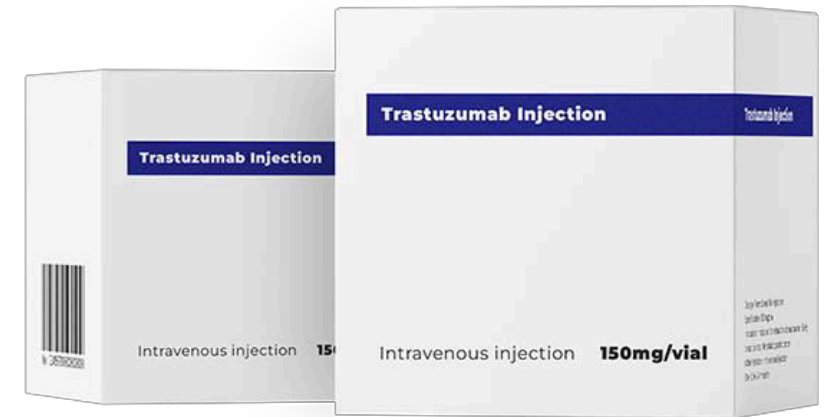
Specification(Dosage): 150mg/vial; (440mg is still in pipeline)

~~Not available: 600mg, 420 mg~~

Indication: Indicated for Metastatic breast cancer, Early breast cancer, Metastatic gastric cancer.

Administration: Intravenous injection

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Avastin®

Manufacturer: Genentech, Inc. (a member of the Roche Group)

Trastuzumab

Pertuzumab Injection

English Name: Pertuzumab Injection

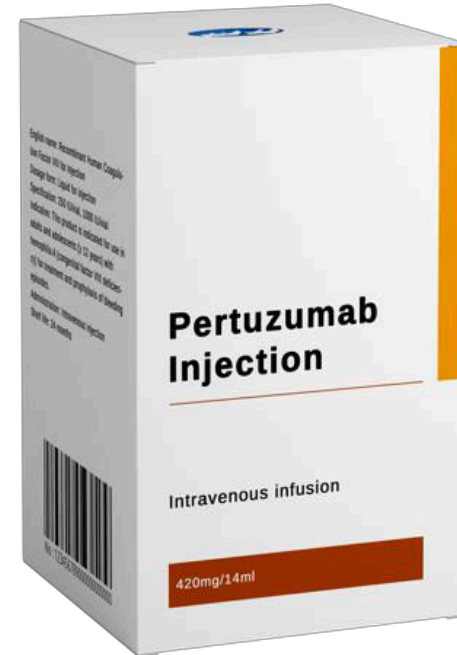
Dosage Form: Solution for injection

Specification(Dosage): 420mg/14mL/vial

Indication: Indicated for HER2-positive metastatic breast cancer, HER2-positive early breast cancer.

Administration: Intravenous infusion

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Perjeta®

Manufacturer: Genentech, Inc. (a member of the Roche Group)

Pertuzumab

Tocilizumab Injection

English Name: Tocilizumab Injection

Dosage Form: Solution for injection

Specification(Dosage): 80mg/4mL/vial

~~Not available: 200mg/10mL, 400mg/20mL~~

Indication: Indicated for rheumatoid arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, cytokine release syndrome.

Administration: Intravenous infusion

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Actemra®

Manufacturer: Genentech, Inc. (a member of the Roche Group)

Tocilizumab

Recombinant Human Coagulation Factor VIII for Injection

English Name: Recombinant Human Coagulation Factor VIII for Injection

Dosage Form: Liquid for injection

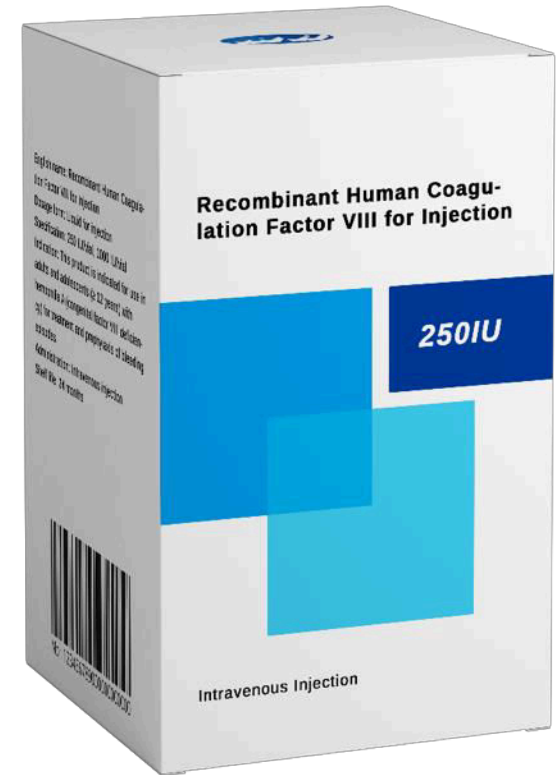
Specification(Dosage): 250 IU/vial, 1000 IU/vial; (500IU is still in pipeline)

~~Not available: 1250IU/vial, 1500IU/vial, 2000IU/vial, 2500IU/vial, etc.~~

Indication: This product is indicated for use in adults and adolescents (≥ 12 years) with hemophilia A (congenital factor VIII deficiency) for treatment and prophylaxis of bleeding episodes.

Administration: Intravenous injection

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Advate® / Kogenate FS® / Eloctate®
Manufacturer: Takeda / Bayer / Sanofi

Human Coagulation Factor VIII for Injection

English Name: Human Coagulation Factor VIII

Dosage Form: Lyophilized powder for injection (with solvent for reconstitution)

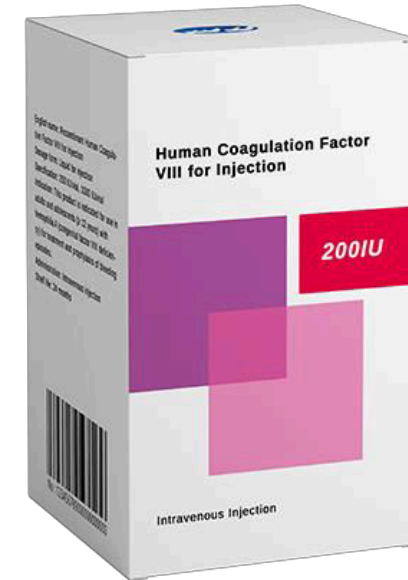
Specification: 200IU /vial, 300IU /vial, 400IU/vial)

~~Not available: 250IU/vial, 1000IU/vial, 1500IU/vial, 2500IU/vial, etc.~~

Indication: Indicated for the treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency).

Administration: Intravenous injection after reconstitution

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Hemofil M® / Koate-DVI® / Octanate®

Manufacturer: Takeda / Grifols / Octapharma

Human Hepatitis B Immunoglobulin

English Name: Human Hepatitis B Immunoglobulin

Dosage Form: Solution for injection

Specification: 100IU/1mL/vial, 200IU/2mL/vial)

~~Not available: 220IU/vial, 500IU/vial, 1100IU/vial, 2000IU/vial, 4000IU/vial, etc.~~

Indication: Indicated for prevention of hepatitis B virus infection following exposure, including needlestick injury, sexual exposure, or perinatal exposure from HBsAg-positive mothers.

Administration: Intramuscular injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: HepaGam B® / Nabi-HB® / HepBQuin®
Manufacturer: Grifols / Emergent BioSolutions / Kedrion Biopharma

Hep-B Immunoglobulin

Human Tetanus Immunoglobulin

English Name: Human Tetanus Immunoglobulin

Dosage Form: Solution for injection

Specification: 250IU/2.5mL/vial

~~Not available: 100IU/vial, 200IU/vial, 500IU/vial, etc.~~

Indication: Indicated for prophylaxis and treatment of tetanus in individuals with inadequate or uncertain tetanus immunization status.

Administration: Intramuscular injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: HyperTET® / Tetagam-P® / Tetanus Immune Globulin (TIG)

Manufacturer: Bio Products Laboratory / Grifols / Sanofi Pasteur

Tetanus Immunoglobulin

Human Rabies Immunoglobulin Injection

English Name: Human Rabies Immunoglobulin Injection

Dosage Form: Solution for injection

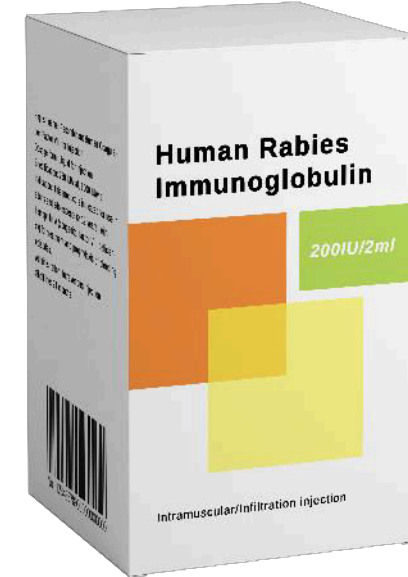
Specification: 200IU/2mL/vial

~~Not available: 300IU/1mL, 900IU/3mL, 1500IU/5mL, etc.~~

Indication: Indicated for post-exposure prophylaxis against rabies, to be administered with rabies vaccine in individuals suspected of rabies virus exposure.

Administration: Infiltration into and around the wound, with any remaining $\frac{1}{2}$ volume given intramuscularly

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Imogam® Rabies-HT / HyperRAB® / Rabies Human Immunoglobulin (HRIG)

Manufacturer: Sanofi Pasteur / Grifols / Kedrion Biopharma

Rabies Immunoglobulin

Insulin Aspart Injection

English Name: Insulin Aspart Injection

Dosage Form: Solution for injection

Specification(Dosage): 3ml: 300 units, Cartridge

~~Not available: 10ml: 1000 units disposable pen, reusable pen, etc.~~

Indication: Diabetes need to be treated by insulin.

Administration: Subcutaneously injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: NovoRapid® / Fiasp®

Manufacturer: Novo Nordisk A/S

Insulin Glargine Injection

English Name: Insulin Glargine Injection

Dosage Form: Solution for injection

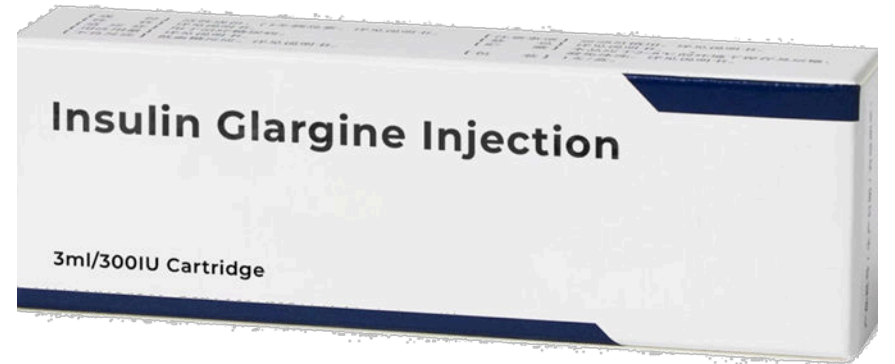
Specification(Dosage): 3ml: 300 units / cartridge/prefilled pen; 10ml: 1000 units/vial

~~Not available: disposable pen, reusable pen, etc.~~

Indication: Diabetes need to be treated by insulin.

Administration: Subcutaneously injection

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Lantus® / Toujeo® / Basaglar®

Manufacturer: Sanofi / Eli Lilly (for Basaglar®)

Glargine

Recombinant Human Basic Fibroblast Growth Factor for External Use (rh-bFGF)

English Name: Recombinant Human Basic Fibroblast Growth Factor for External Use

Dosage Form: Freeze-dried powder

Specification(Dosage): 20,000IU/vial, 35,000IU/vial, 70,000IU/vial, 300,000IU/vial

Indication: Promote wound healing and can be used for chronic wounds (including chronic granulation wounds, ulcers and bedsores, etc.), fresh wounds (including trauma, surgical wounds, etc.) and burn wounds (including superficial partial thickness, deep partial thickness and granulation wounds).

Administration: Administer the product every other day.

✓ **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Trafermin/Fiblast®

Manufacturer: Trafermin (brand name Fiblast)

Human Epidermal Growth Factor Eye Drops

English Name: Human Epidermal Growth Factor Eye Drops

Dosage Form: Colorless and clear liquid

Specification(Dosage): 20,000IU(40 μ g)/2ml/vial, 30,000IU(60 μ g)/3ml/vial, 40,000(80 μ g) /4ml/vial

Indication: It is indicated for the treatment of corneal transplantation and the treatment after operation of pterygium.

Administration: For eye dropping, 2-3 drops each time, four times a day.

✓ **BE Study Available**



Human Growth Hormone for Injection

English Name: Human Growth Hormone for Injection

Dosage Form: Liquid for injection

Specification(Dosage): 4IU/1.33mg/vial or prefilled syringes

Indication: Indicated for Growth Disturbance in infants, children and adolescents; Short bowel syndrome in adults; Treatment for severely burned patients.

Administration: Subcutaneous injection

 **BE Study Available**



Levonorgestrel Silastic Implants

English Name: Levonorgestrel Silastic Implants

Dosage Form: Two flexible cylindrical capsule implants, each containing 75 mg of the progestin levonorgestrel. The total administered (implanted) dose is 150 mg

Specification(Dosage): 75mg/Polymer rod, 2 Polymer rods per box

Indication: Long-acting reversible birth control. It primarily works by stopping ovulation and by thickening the mucus around the cervix.

Administration: During the first week of the menstrual cycle (starting from the first day of menstruation), under local anesthesia and sterile conditions, make a 0.2 cm incision on the skin of the upper arm or inner thigh. Use a cannula to insert the implant under the skin. Apply a band-aid on the wound and cover it with gauze.



✓ **BE Study Available**



Chemical Products

Products	Dosage	Dosage Forms	Indication
SRA Liraglutide Injection	18 mg/ 3 ml	Disposable Pen	Type 2 diabetes mellitus, weight management in certain patients.
SRA Enzalutamide Soft Capsule	40mg	Soft Capsule	Metastatic castration-resistant prostate cancer.
SRA Eribulin Mesilate Injection	2ml:1mg	Injection	Metastatic breast cancer, liposarcoma.
SRA Bivalirudin for Injection	250mg	Injection	Anticoagulation in percutaneous coronary intervention.
SRA Paclitaxel for Injection (Albumin Bound)	100mg	Injection	Breast, lung, pancreatic cancer; Kaposi's sarcoma.
Olaparib Tablets	100mg, 150mg	Tablets	BRCA-mutated ovarian, breast, pancreatic, prostate cancers.
Sorafenib Tosylate Tablets	0.2g	Tablets	Liver, kidney, thyroid cancers.
Tenofovir Alafenamide Fumarate Tablets	25mg	Tablets	Chronic hepatitis B, HIV infection.
Doxazosin Mesylate Extended-Release Tablets	4mg	Tablets	Hypertension, benign prostatic hyperplasia.

Liraglutide Injection

SRA
APPROVED

English Name: Liraglutide Injection

Dosage Form: Solution for injection in pre-filled pen

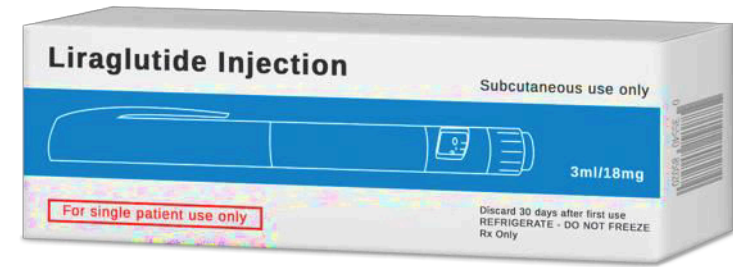
Specification(Dosage): 18mg/3mL (disposable pen)

Indication: Indicated for type 2 diabetes mellitus.

Administration: Subcutaneous injection

Registration Category: Chemical Products

Approval by Stringent Regulatory Authorities: Yes



✓ **BE Study Available**

ORIGINATOR INFORMATION

Brand Name: Victoza® / Saxenda®

Manufacturer: Novo Nordisk A/S

Liraglutide (CS)

Enzalutamide Soft Capsules

English Name: Enzalutamide Soft Capsules

Dosage Form: Soft capsules/Tablets

Specification(Dosage):

40mg/capsule, 112 Capsules/Box

40mg/tablet, 80mg/tablet, 112 Tablets/Box

Indication: Indicated for metastatic castration-resistant prostate cancer, metastatic hormone-sensitive prostate cancer, and non-metastatic castration-resistant prostate cancer.

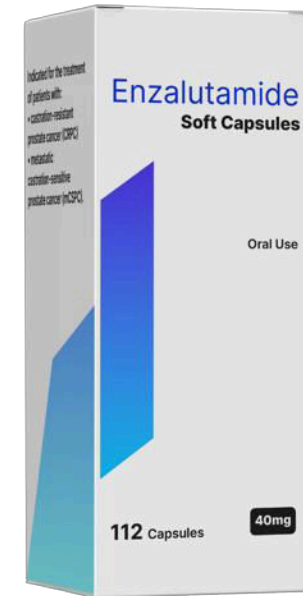
Administration: Oral administration

Approval by Stringent Regulatory Authorities: Yes

 **BE Study Available**

Enzalutamide

SRA
APPROVED



ORIGINATOR INFORMATION

Brand Name: Xtandi®

Manufacturer: Astellas Pharma Inc.

Eribulin Mesilate Injection

English Name: Eribulin Mesilate Injection

Dosage Form: Solution for injection

Specification(Dosage): 2mL:1mg/vial

Indication: Indicated for metastatic breast cancer and unresectable or metastatic liposarcoma.

Administration: Intravenous injection

Approval by Stringent Regulatory Authorities: Yes

 **BE Study Available**

Eribulin Mesilate

SRA
APPROVED



ORIGINATOR INFORMATION

Brand Name: Halaven®

Manufacturer: Eisai Co., Ltd.

Paclitaxel for Injection (Albumin Bound)

English Name: Paclitaxel for Injection (Albumin Bound)

Dosage Form: Lyophilized powder for injection

Specification(Dosage): 100mg/vial

Indication: Indicated for metastatic breast cancer, non-small cell lung cancer, and metastatic adenocarcinoma of the pancreas.

Administration: Intravenous infusion

Approval by Stringent Regulatory Authorities: Yes

 **BE Study Available**



SRA
APPROVED

ORIGINATOR INFORMATION

Brand Name: Abraxane®

Manufacturer: Celgene Corporation (now part of Bristol-Myers Squibb)

Paclitaxel (Albumin)

Bivalirudin for Injection

English Name: Bivalirudin for Injection

Dosage Form: Lyophilized powder for injection

Specification(Dosage): 250mg/vial

Indication: Indicated as an anticoagulant in patients with unstable angina undergoing percutaneous coronary intervention (PCI) and in patients with or at risk of heparin-induced thrombocytopenia undergoing PCI.

Administration: Intravenous injection

Approval by Stringent Regulatory Authorities: Yes

 **BE Study Available**



SRA
APPROVED

ORIGINATOR INFORMATION

Brand Name: Angiomax®

Manufacturer: The Medicines Company / Novartis (depending on region)

Bivalirudin

Olaparib Tablets

English Name: Olaparib Tablets

Dosage Form: Tablet

Specification(Dosage): 100mg/tablet, 150mg/tablet

Indication: Ovarian cancer—for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. Breast cancer—in patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

Administration: Taken orally twice daily

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Lynparza®

Manufacturer: AstraZeneca

Olaparib

Sorafenib Tosylate Tablets

English Name: Sorafenib Tosylate Tablets

Dosage Form: Tablets

Specification(Dosage): 0.2g/tablet

Indication: Indicated for unresectable hepatocellular carcinoma, advanced renal cell carcinoma, and differentiated thyroid carcinoma refractory to radioactive iodine treatment.

Administration: Oral administration

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Nexavar®

Manufacturer: Bayer AG

Sorafenib Tosylate

Tenofovir Alafenamide Fumarate Tablets

English Name: Tenofovir Alafenamide Fumarate Tablets

Dosage Form: Tablets

Specification(Dosage): 25mg/tablet

Indication: Indicated for chronic hepatitis B virus infection in adults and adolescents (≥ 12 years of age, weighing at least 35 kg).

Administration: Oral administration

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Vemlidy® / Descovy®

Manufacturer: Gilead Sciences, Inc.

Tenofovir

Doxazosin Mesylate Extended-Release Tablets

English Name: Doxazosin Mesylate Extended-Release Tablets

Dosage Form: Extended-release tablets

Specification: 4mg/tablet

Indication: Indicated for the treatment of hypertension and the treatment of signs and symptoms of benign prostatic hyperplasia (BPH).

Administration: Oral administration

 **BE Study Available**



ORIGINATOR INFORMATION

Brand Name: Cardura XL®

Manufacturer: Pfizer Inc.

Doxazosin



Pipeline Products

Key Pipeline Products

Pre-Clinical
Research

Phase I

Phase II

Phase III

Application &
Approval

Recombinant Herpes Zoster Vaccine

23-Valent Pneumococcal Polysaccharide Vaccine

Measles, Mumps, and Rubella (MMR)

Denosumab Injection

Rituximab Injection

Axitinib Tablets

Abemaciclib Tablets

■ Vaccines ■ Bio-pharmaceuticals ■ Chemicals

Denosumab Injection

English Name: Denosumab Injection

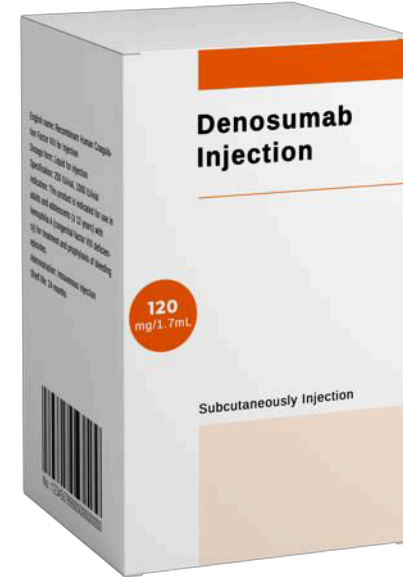
Dosage Form: Solution for injection

Specification(Dosage): 120mg/1.7mL

Indication: Indicated for osteoporosis in postmenopausal women and men at increased risk of fracture, and for prevention of skeletal-related events in patients with bone metastases from solid tumors.

Administration: Subcutaneous injection

To be launched in 2026



Rituximab Injection

English Name: Rituximab Injection

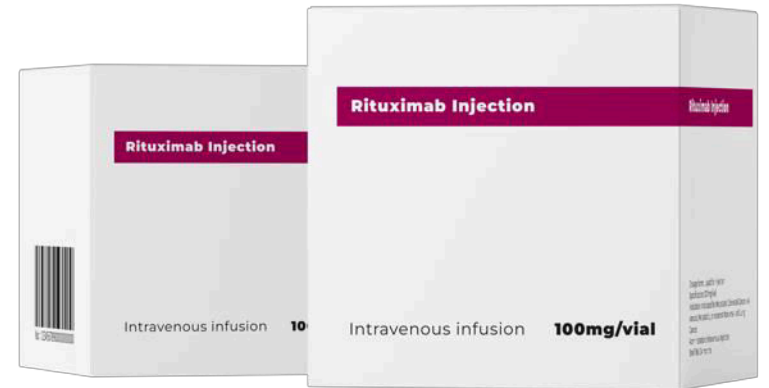
Dosage Form: Solution for infusion

Specification(Dosage): 100mg/10mL; 500mg/50mL

Indication: Indicated for non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, and other CD20-positive B-cell related disorders.

Administration: Intravenous infusion

To be launched in 2026



Axitinib Tablets

English Name: Axitinib Tablets

Dosage Form: Tablets

Specification(Dosage): 5mg/tablet

Indication: Indicated for advanced renal cell carcinoma after failure of one prior systemic therapy.

Administration: Oral administration

To be launched between 2026-2027



Abemaciclib Tablets

English Name: Abemaciclib Tablets

Dosage Form: Tablets

Specification(Dosage): 150mg/tablet

Indication: Indicated for hormone receptor-positive, HER2-negative advanced or metastatic breast cancer.

Administration: Oral administration

To be launched between 2026-2027



Recombinant Herpes Zoster Vaccine (CHO Cell)

English Name: Recombinant Herpes Zoster Vaccine (CHO Cell)

Dosage Form: Suspension for injection

Specification(Dosage): 0.5 ml/vial/dose

Indication: A vaccine indicated for prevention of herpes zoster (HZ) (shingles) in adults aged 40 years and older.

Administration: Intramuscular injection; Two doses (0.5 mL each) administered according to the following schedules: A first dose at Month 0 followed by a second dose administered at least 2 months later.

To be launched in 2026



23-Valent Pneumococcal Polysaccharide Vaccine

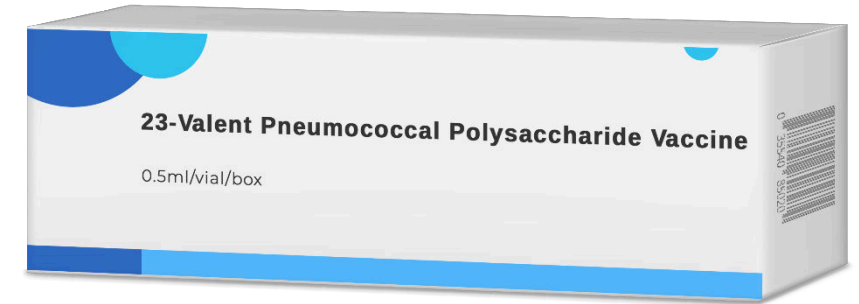
English Name: 23-Valent Pneumococcal Polysaccharide Vaccine

Dosage Form: Solution for injection

Specification: 0.5mL/dose

Indication: Indicated for active immunization to prevent pneumococcal disease caused by the 23 serotypes contained in the vaccine, recommended for adults ≥ 50 years and individuals ≥ 2 years at increased risk of pneumococcal infection.

Administration: Intramuscular injection



Measles, Mumps, and Rubella Vaccine (MMR)

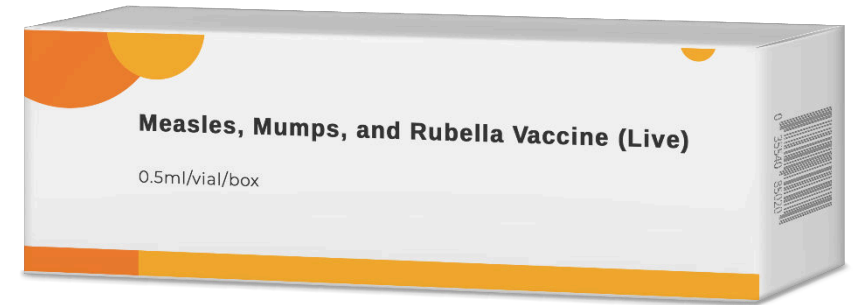
English Name: Measles, Mumps, and Rubella Vaccine (MMR)

Dosage Form: Freeze-dried powder for injection

Specification: 0.5mL/dose

Indication: Indicated for active immunization against measles, mumps, and rubella in children and susceptible adults.

Administration: Intramuscular injection



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www.mellowhope.com



sales@mellowhope.com



+86-755-82720498



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