

## BCG vaccine

## Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

## Indications

Need for immunization against tuberculosis

## Japanese encephalitis vaccine

## Section

Recommendations for certain regions  
All vaccines should comply with the WHO requirements for biological substances.

## Indications

Need for immunization against certain single viral diseases

## Adalimumab

## Section

Immunomodulators for non-malignant disease  
Parenteral > General injections > SC: 40 mg per 0.8 mL; 40 mg per 0.4 mL;  
10 mg per 0.2 mL; 20 mg per 0.4 mL

Medicines for juvenile joint diseases

Parenteral > General injections > SC: 40 mg per 0.8 mL; 40 mg per 0.4 mL;  
10 mg per 0.2 mL; 20 mg per 0.4 mL

## Indications

Axial spondyloarthritis

Crohn disease site

Rheumatoid arthritis

Juvenile idiopathic arthritis

## Ansuvimab

## Section

Medicines for Ebola virus disease  
Parenteral > General injections > IV: 400 mg powder for injection

## Indications

Ebola virus disease

## Anti-D immunoglobulin

## Section

Human immunoglobulins  
Parenteral > General injections > IV: 250 µg in single-dose vial  
Parenteral > General injections > IM: 250 µg in single-dose vial

## Indications

Maternal care for red cell antibodies

Rh incompatibility reaction

## Anti-rabies immunoglobulin

### Section

Human immunoglobulins

Parenteral > General injections > IM: 150 IU per mL in vial

Parenteral > Locoregional injections > Other: 150 IU per mL in vial

### Indications

Rabies

## Anti-rabies virus monoclonal antibodies

### Section

Immunologicals > Sera, immunoglobulins and monoclonal antibodies

Parenteral > Locoregional injections > Intradermal: 40 IU per mL in 1.25 mL vial (human); 40 IU per mL in 2.5 mL vial (human); 100 IU per mL in 2.5 mL vial (human); 300 IU per mL in 10 mL vial (murine); 600 IU per mL in 1 mL vial (murine); 600 IU per mL in 2.5 mL vial (murine); 600 IU per mL in 5 mL vial (murine)

### Indications

Rabies

## Anti-tetanus immunoglobulin

### Section

Human immunoglobulins

Parenteral > General injections > IM: 500 IU in vial

### Indications

Tetanus

## Antivenom immunoglobulin

### Section

Immunologicals > Sera, immunoglobulins and monoclonal antibodies

Parenteral > General injections > IV:

### Indications

Harmful effects of or exposure to noxious substances, chiefly nonmedicinal as to source, not elsewhere classified

## Asparaginase

### Section

Cytotoxic medicines

Powder for injection: 10 000 IU in vial.

Parenteral > General injections > unspecified: 10000 IU in vial powder for injection

### Indications

Unspecified malignant neoplasms of ill-defined or unspecified sites

Lymphoid leukaemia, not elsewhere classified

## Atezolizumab

### Section

Immunomodulators

### Indications

Therapeutic equivalent to pembrolizumab for

Other specified malignant neoplasms of bronchus or lung

## Atoltivimab + maftivimab + odesivimab

### Section

Medicines for Ebola virus disease

Parenteral > General injections > IV: 241.7 mg + 241.7 mg + 241.7 mg in 14.5 mL vial

### Indications

Ebola virus disease

## Axicabtagene ciloleucel

### Section

Antineoplastics and supportive medicines

Cell suspension for infusion:  $2 \times 10^6$  anti-CD19 CAR-positive viable T-cells per kg of body weight.

### Indications

Diffuse large B-cell lymphomas

## Bevacizumab

### Section

Ophthalmological preparations > Anti-vascular endothelial growth factor (VEGF) preparations

Parenteral > Locoregional injections > Intravitreal: 25 mg per mL

### Indications

Age related macular degeneration

## Cemiplimab

### Section

Immunomodulators

### Indications

Therapeutic equivalent to pembrolizumab for

Other specified malignant neoplasms of bronchus or lung

## Certolizumab pegol

### Section

Immunomodulators for non-malignant disease

### Indications

Therapeutic equivalent to adalimumab for

Axial spondyloarthritis

Therapeutic equivalent to adalimumab for

Crohn disease site

Therapeutic equivalent to adalimumab for

Rheumatoid arthritis

Medicines for juvenile joint diseases

Therapeutic equivalent to adalimumab for

Juvenile idiopathic arthritis

## Cholera vaccine

### Section

Recommendations for some high-risk populations  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against cholera alone

## Coagulation factor IX

### Section

Blood coagulation factors  
Parenteral > General injections > IV: 500 IU in vial powder for injection;  
1000 IU in vial powder for injection

### Indications

Coagulation defects, purpura or other haemorrhagic or related conditions

Haemophilia B

## Coagulation factor IX complex

### Section

Blood coagulation factors

### Indications

Therapeutic equivalent to coagulation factor IX for

Coagulation defects, purpura or other haemorrhagic or related conditions

Therapeutic equivalent to coagulation factor IX for

Haemophilia B

## Coagulation factor VIII

### Section

Blood coagulation factors  
Parenteral > General injections > IV: 250 IU in vial powder for injection;  
500 IU in vial powder for injection; 1000 IU in vial powder for injection

### Indications

Haemophilia A

## Cryoprecipitate (not pathogen-reduced)

### Section

Blood and blood components

### Indications

Therapeutic equivalent to cryoprecipitate (pathogen-reduced) for

Haemophilia A

Therapeutic equivalent to cryoprecipitate (pathogen-reduced) for

Coagulation defects, purpura or other haemorrhagic or related conditions

Therapeutic equivalent to cryoprecipitate (pathogen-reduced) for

Von Willebrand disease

Therapeutic equivalent to cryoprecipitate (pathogen-reduced) for

Obstetric haemorrhage

## Cryoprecipitate (pathogen-reduced)

### Section

Blood and blood components

Injection: frozen liquid in bag or lyophilized powder in vial containing:

> 50 IU Factor VIII

> 100 IU vWF

> 140 mg clottable fibrinogen per unit

### Indications

Haemophilia A

Coagulation defects, purpura or other haemorrhagic or related conditions

Von Willebrand disease

Obstetric haemorrhage

## Dalteparin

### Section

Medicines affecting coagulation

### Indications

Therapeutic equivalent to enoxaparin for

Acute ischaemic heart disease

Therapeutic equivalent to enoxaparin for

Venous thromboembolism

## Darbepoetin alfa

### Section

Antianaemia medicines

### Indications

Therapeutic equivalent to erythropoiesis-stimulating agents for

Anaemia due to chronic disease

## Dengue vaccine

### Section

Recommendations for some high-risk populations  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against certain single viral diseases

## Diphtheria antitoxin

### Section

Immunologicals > Sera, immunoglobulins and monoclonal antibodies  
Parenteral > General injections > IM: 10000 IU in vial; 20000 IU in vial

### Indications

Need for immunization against diphtheria alone

## Diphtheria vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against diphtheria alone

## Enoxaparin

### Section

Medicines affecting coagulation  
Parenteral > General injections > SC: 20 mg per 0.2 mL in prefilled syringe; 40 mg per 0.4 mL in prefilled syringe; 60 mg per 0.6 mL in prefilled syringe; 80 mg per 0.8 mL in prefilled syringe; 100 mg per 1 mL in prefilled syringe; 120 mg per 0.8 mL in prefilled syringe; 150 mg per 1 mL in prefilled syringe; 150 mg per 1 mL in ampoule; 20 mg per 0.2 mL in ampoule; 40 mg per 0.4 mL in ampoule; 60 mg per 0.6 mL in ampoule; 80 mg per 0.8 mL in ampoule; 100 mg per 1 mL in ampoule; 120 mg per 0.8 mL in ampoule

### Indications

Acute ischaemic heart disease

Venous thromboembolism

## Epoetin alfa

### Section

Antianaemia medicines

### Indications

Therapeutic equivalent to erythropoiesis-stimulating agents for

Anaemia due to chronic disease

## Epoetin beta

### Section

Antianaemia medicines

### Indications

Therapeutic equivalent to erythropoiesis-stimulating agents for

Anaemia due to chronic disease

## Epoetin theta

### Section

Antianaemia medicines

### Indications

Therapeutic equivalent to erythropoiesis-stimulating agents for

Anaemia due to chronic disease

## Equine rabies immunoglobulin

### Section

Immunologicals > Sera, immunoglobulins and monoclonal antibodies  
Parenteral > Locoregional injections > Intradermal: 150 IU per mL in vial;  
200 IU per mL in vial; 300 IU per mL in vial; 400 IU per mL in vial

### Indications

Rabies

## Erythropoiesis-stimulating agents

### Section

Antianaemia medicines  
Parenteral > General injections > unspecified: 1000 IU per 0.5 mL pre-filled syringe; 2000 IU per 0.5 mL pre-filled syringe; 3000 IU per 0.3 mL pre-filled syringe; 4000 IU per 0.4 mL pre-filled syringe; 5000 IU per 0.5 mL pre-filled syringe; 6000 IU per 0.6 mL pre-filled syringe; 8000 IU per 0.8 mL pre-filled syringe; 10000 IU per 1 mL pre-filled syringe; 20000 IU per 0.5 mL pre-filled syringe; 40000 IU per 1 mL pre-filled syringe

### Indications

Anaemia due to chronic disease

## Etanercept

### Section

Immunomodulators for non-malignant disease

### Indications

Therapeutic equivalent to adalimumab for

Axial spondyloarthritis

Therapeutic equivalent to adalimumab for

Crohn disease site

Therapeutic equivalent to adalimumab for

Rheumatoid arthritis

Medicines for juvenile joint diseases

Therapeutic equivalent to adalimumab for

Juvenile idiopathic arthritis

## Filgrastim

### Section

#### Immunomodulators

Parenteral > General injections > SC: 120 µg per 0.2 mL in prefilled syringe; 300 µg per 0.5 mL in prefilled syringe; 480 µg per 0.8 mL in prefilled syringe; 300 µg per mL in 1 mL vial; 480 µg per 1.6 mL in 1.6 mL vial

### Indications

Acquired neutropaenia

## Fresh-frozen plasma

### Section

#### Blood and blood components

Parenteral > General injections > IV:

### Indications

Blood transfusion without reported diagnosis

## Golimumab

### Section

#### Immunomodulators for non-malignant disease

#### Medicines for juvenile joint diseases

### Indications

Therapeutic equivalent to [adalimumab](#) for

Axial spondyloarthritis

Therapeutic equivalent to [adalimumab](#) for

Crohn disease site

Therapeutic equivalent to [adalimumab](#) for

Rheumatoid arthritis

Therapeutic equivalent to [adalimumab](#) for

Juvenile idiopathic arthritis

## Haemophilus influenzae type b vaccine

### Section

#### Recommendations for all immunization programmes

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against single bacterial diseases

## Hepatitis A vaccine

### Section

#### Recommendations for some high-risk populations

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against viral hepatitis



## Hepatitis B vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against viral hepatitis

## Human papilloma virus (HPV) vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against certain single viral diseases

## Infliximab

### Section

Immunomodulators for non-malignant disease

Medicines for juvenile joint diseases

### Indications

Therapeutic equivalent to adalimumab for

Axial spondyloarthritis

Therapeutic equivalent to adalimumab for

Crohn disease site

Therapeutic equivalent to adalimumab for

Rheumatoid arthritis

Therapeutic equivalent to adalimumab for

Juvenile idiopathic arthritis

## Influenza vaccine (seasonal)

### Section

Recommendations for immunization programmes with certain characteristics  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against influenza

## Insulin

### Section

Insulins  
Parenteral > General injections > SC: 40 IU per mL in 10 mL vial (soluble); 100 IU per mL in 10 mL vial (soluble); 100 IU per mL in 3 mL cartridge (soluble); 100 IU per mL in 3 mL pre-filled pen (soluble)

### Indications

Type 2 diabetes mellitus

Type 1 diabetes mellitus

## Insulin degludec

### Section

#### Insulins

### Indications

Therapeutic equivalent to long-acting insulin analogues for

Type 1 diabetes mellitus

Therapeutic equivalent to long-acting insulin analogues for

Type 2 diabetes mellitus

## Insulin detemir

### Section

#### Insulins

### Indications

Therapeutic equivalent to long-acting insulin analogues for

Type 1 diabetes mellitus

Therapeutic equivalent to long-acting insulin analogues for

Type 2 diabetes mellitus

## Insulin glargine

### Section

#### Insulins

### Indications

Therapeutic equivalent to long-acting insulin analogues for

Type 1 diabetes mellitus

Therapeutic equivalent to long-acting insulin analogues for

Type 2 diabetes mellitus

## Intermediate-acting insulin

### Section

#### Insulins

Parenteral > General injections > SC: 40 IU per mL in 10 mL vial as compound insulin zinc suspension or isophane insulin; 100 IU per mL in 10 mL vial as compound insulin zinc suspension or isophane insulin; 100 IU per mL in 3 mL cartridge as compound insulin zinc suspension or isophane insulin; 100 IU per mL in 3 mL pre-filled pen as compound insulin zinc suspension or isophane insulin

### Indications

Type 1 diabetes mellitus

Type 2 diabetes mellitus

## Lisocabtagene maraleucel

### Section

Antineoplastics and supportive medicines

### Indications

Therapeutic equivalent to axicabtagene ciloleucel for

Diffuse large B-cell lymphomas

## Long-acting insulin analogues

### Section

Insulins

Parenteral > General injections > SC: 100 IU per mL in 3 mL cartridge; 100 IU per mL in 3 mL pre-filled pen

### Indications

Type 1 diabetes mellitus

Type 2 diabetes mellitus

## Measles vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against measles alone

## Meningococcal meningitis vaccine

### Section

Recommendations for some high-risk populations  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against single bacterial diseases

## Methoxy polyethylene glycol-epoetin beta

### Section

Antianaemia medicines

### Indications

Therapeutic equivalent to erythropoiesis-stimulating agents for

Anaemia due to chronic disease

## Mumps vaccine

### Section

Recommendations for immunization programmes with certain characteristics  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against mumps alone

## Nadroparin

### Section

Medicines affecting coagulation

### Indications

Therapeutic equivalent to enoxaparin for

Acute ischaemic heart disease

Therapeutic equivalent to enoxaparin for

Venous thromboembolism

## Nivolumab

### Section

Immunomodulators

Parenteral > General injections > IV: 10 mg per mL concentrate solution for infusion

### Indications

Melanoma of skin

## Normal immunoglobulin

### Section

Human immunoglobulins

Parenteral > General injections > IV: 5% protein solution; 10% protein solution

Parenteral > General injections > IM: 16% protein solution

Parenteral > General injections > SC: 15% protein solution; 16% protein solution

### Indications

Langerhans cell histiocytosis

Primary immunodeficiencies

Mucocutaneous lymph node syndrome

## Ocrelizumab

### Section

Medicines for multiple sclerosis

Parenteral > General injections > IV: 30 mg per mL in 10 vial concentrate for solution

### Indications

Multiple sclerosis

## Pegaspargase

### Section

Cytotoxic medicines

Parenteral > General injections > IV: 3750 units per 5 mL in vial; 3750 units in vial powder for injection

### Indications

Lymphoid leukaemia, not elsewhere classified

## Pegfilgrastim

### Section

Immunomodulators

Parenteral > General injections > SC: 6 mg per 0.6 mL in pre-filled syringe

### Indications

Acquired neutropaenia

## Pegylated interferon alfa (2a)

### Section

Medicines for hepatitis C > Other antivirals for hepatitis C  
Parenteral > General injections > SC: 180 µg in vial; 180 µg in prefilled syringe

### Indications

Chronic hepatitis C

## Pegylated interferon alfa (2b)

### Section

Medicines for hepatitis C > Other antivirals for hepatitis C  
Parenteral > General injections > SC: 80 µg in prefilled syringe; 100 µg in prefilled syringe

### Indications

Chronic hepatitis C

## Pembrolizumab

### Section

Immunomodulators  
Parenteral > General injections > IV: 50 mg powder for injection

### Indications

Therapeutic equivalent to nivolumab for

Melanoma of skin

Other specified malignant neoplasms of bronchus or lung

## Pertussis vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against pertussis alone

## Platelets

### Section

Blood and blood components  
Parenteral > General injections > IV:

### Indications

Blood transfusion without reported diagnosis

## Pneumococcal vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against single bacterial diseases

## Poliomyelitis vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against poliomyelitis

## Rabies vaccine

### Section

Recommendations for some high-risk populations  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against rabies

## Red blood cells

### Section

Blood and blood components  
Parenteral > General injections > IV:

### Indications

Blood transfusion without reported diagnosis

## Rituximab

### Section

Targeted therapies  
Parenteral > General injections > IV: 100 mg per 10 mL in 10 mL vial; 500 mg per 50 mL in 50 mL vial

Medicines for multiple sclerosis  
Parenteral > General injections > IV: 500 mg per 50 mL in 50 mL vial

### Indications

Follicular lymphoma

Chronic lymphocytic leukaemia or small lymphocytic lymphoma

Diffuse large B-cell lymphomas

Burkitt lymphoma including Burkitt leukaemia

Multiple sclerosis

## Rotavirus vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against certain single viral diseases

## Rubella vaccine

### Section

Recommendations for all immunization programmes  
All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against rubella alone

## Surfactant

### Section

Medicines administered to the neonate [c]

Respiratory > Suspension: 80 mg per mL for intratracheal instillation; 25 mg per mL for intratracheal instillation

### Indications

Respiratory distress syndrome of newborn

## Tetanus vaccine

### Section

Recommendations for all immunization programmes

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against tetanus alone

## Tick-borne encephalitis vaccine

### Section

Recommendations for certain regions

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against arthropod-borne viral encephalitis

## Tisagenlecleucel

### Section

Antineoplastics and supportive medicines

### Indications

Therapeutic equivalent to axicabtagene ciloleucel for

Diffuse large B-cell lymphomas

## Tislelizumab

### Section

Immunomodulators

Parenteral > General injections > IV: 100 mg per 10 mL

### Indications

Other specified malignant neoplasms of bronchus or lung

## Toripalimab

### Section

Immunomodulators

Parenteral > General injections > IV: 240 mg per 6 mL in vial

### Indications

Malignant neoplasms of nasopharynx

Malignant neoplasms of oesophagus

## Trastuzumab

### Section

#### Targeted therapies

Parenteral > General injections > IV: 60 mg in vial powder for injection; 150 mg in vial powder for injection; 440 mg in vial powder for injection

### Indications

Carcinoma of breast, specialised type

## Typhoid vaccine

### Section

#### Recommendations for some high-risk populations

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against typhoid-paratyphoid alone

## Ustekinumab

### Section

Dermatological medicines > Medicines affecting skin differentiation and proliferation

Parenteral > General injections > SC: 45 mg per 0.5 mL in vial; 90 mg per mL in pre-filled syringe

### Indications

Psoriasis of unspecified type

## Varicella vaccine

### Section

Recommendations for immunization programmes with certain characteristics

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against certain single viral diseases

## Whole blood

### Section

Blood and blood components

Parenteral > General injections > IV:

### Indications

Blood transfusion without reported diagnosis

## Yellow fever vaccine

### Section

Recommendations for certain regions

All vaccines should comply with the WHO requirements for biological substances.

### Indications

Need for immunization against certain single viral diseases