

# CONTENTS OF SUPPLEMENT 11.8

*Lists of the monographs and general chapters that, for Supplement 11.8, are new, revised or corrected or have had their titles changed, are given below.*

*As of the 11<sup>th</sup> Edition, all revised, corrected or deleted parts of a text published in the online version of the European Pharmacopoeia are indicated by change marks in the form of triangles. For reasons of readability, these triangles are not shown in the print version.*

*Corrected texts are to be taken into account as soon as possible and not later than the end of the month following the month of publication of the edition or supplement. New and revised texts are to be taken into account not later than the implementation date.*

*A QR code is included at the start of each text, providing a link to further information on the text (stored in the Knowledge database) for smartphones and tablets with a camera and a compatible app.*

*Individual copies of texts published in this edition will not be supplied.*

*Subscribers to the current version (print or online) of the European Pharmacopoeia have access to an online archive version of all obsolete editions and supplements of the European Pharmacopoeia in PDF format.*

## NEW TEXTS

*The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on 1 July 2025 at the latest.*

### GENERAL CHAPTERS

- 2.5.44. Capillary isoelectric focusing for recombinant therapeutic monoclonal antibodies
- 5.1.13. Pyrogenicity

### MONOGRAPHS

#### Dosage forms

Orodispersible films (3195)

#### Herbal drugs and herbal drug preparations

White mulberry leaf (3164)

### Homoeopathic preparations

Iberis amara for homoeopathic preparations (2838)

### Monographs

- Dapagliflozin propylene glycol monohydrate (3137)
- Dapagliflozin propylene glycol tablets (3175)
- Memantine hydrochloride (2773)
- Olodaterol hydrochloride (3174)
- Rosuvastatin zinc tetrahydrate (3135)

## REVISED TEXTS

*The following texts have been technically revised since their last publication. They will be implemented on 1 July 2025 at the latest.*

### GENERAL CHAPTERS

- 2.4.20. Determination of elemental impurities
- 2.6.30. Monocyte-activation test
- 2.6.40. Monocyte-activation test for vaccines containing inherently pyrogenic components
- 2.7.24. Flow cytometry
- 3.1.3. Polyolefins
- 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations
- 3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.7. Sets for the transfusion of blood and blood components
- 4. Reagents
- 5.1.10. Guidelines for using the test for bacterial endotoxins

- 5.2.6. Evaluation of safety of veterinary vaccines and immunosera
- 5.2.7. Evaluation of efficacy of veterinary vaccines and immunosera
- 5.2.11. Carrier proteins for the production of conjugated polysaccharide vaccines for human use
- 5.22. Names of herbal drugs used in traditional Chinese medicine
- 5.31. Phage therapy medicinal products
- 5.34. Additional information on gene therapy medicinal products for human use

### MONOGRAPHS

#### General monographs

- Immunosera for human use, animal (0084)
- Pharmaceutical preparations (2619)
- Radiopharmaceutical preparations (0125)
- Substances for pharmaceutical use (2034)
- Vaccines for human use (0153)
- Vaccines for veterinary use (0062)

#### Dosage forms

- Intravesical preparations (2811)
- Oromucosal preparations (1807)
- Parenteral preparations (0520)
- Preparations for irrigation (1116)

**Vaccines for human use**

Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)

Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)

Haemophilus type b and meningococcal group C conjugate vaccine (2622)

Haemophilus type b conjugate vaccine (1219)

Hepatitis B vaccine (rDNA) (1056)

Meningococcal group A, C, W135 and Y conjugate vaccine (3066)

Meningococcal group C conjugate vaccine (2112)

Meningococcal polysaccharide vaccine (0250)

Pneumococcal polysaccharide conjugate vaccine (adsorbed) (2150)

Pneumococcal polysaccharide vaccine (0966)

Rabies vaccine for human use prepared in cell cultures (0216)

Tick-borne encephalitis vaccine (inactivated) (1375)

**Vaccines for veterinary use**

Salmonella Enteritidis vaccine (live, oral) for chickens (2520)

Salmonella Typhimurium vaccine (live, oral) for chickens (2521)

**Radiopharmaceutical preparations**

Gallium (<sup>68</sup>Ga) chloride (generator-produced) solution for radiolabelling (2464)

Technetium (<sup>99m</sup>Tc) human albumin injection (0640)

Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations (2294)

**Herbal drugs and herbal drug preparations**

Ash leaf (1600)

Black horehound (1858)

Burdock root (2943)

Horse-chestnut bark (2945)

Moutan bark (2474)

Narrow-leaved coneflower root (1821)

Pale coneflower root (1822)

Pumpkin seed (2941)

Purple coneflower herb (1823)

Purple coneflower root (1824)

Ribwort plantain (1884)

Rosemary leaf (1560)

**Homoeopathic preparations**

Cuprum aceticum for homoeopathic preparations (2146)

**Monographs**

Amikacin sulfate (1290)

Anticoagulant and preservative solutions for human blood (0209)

Anti-T lymphocyte immunoglobulin for human use, animal (1928)

Bovine serum (2262)

Calcium levulinate dihydrate (1296)

Chloramphenicol sodium succinate (0709)

Chlorhexidine digluconate solution (0658)

Colistimethate sodium (0319)

3-O-Desacyl-4'-monophosphoryl lipid A (2537)

Dicloxacillin sodium monohydrate (0663)

Doxapram hydrochloride monohydrate (1201)

Flucloxacillin sodium monohydrate (0668)

Flumetasone pivalate (1327)

Glucose (0177)

Glucose monohydrate (0178)

Haemodialysis, solutions for (0128)

Haemofiltration and haemodiafiltration, solutions for (0861)

Human albumin solution (0255)

Human alpha-1-proteinase inhibitor (2387)

Human antithrombin III concentrate (0878)

Human C1-esterase inhibitor (2818)

Human coagulation factor VII (1224)

Human coagulation factor VIII (0275)

Human coagulation factor IX (1223)

Human coagulation factor XI (1644)

Human fibrinogen (0024)

Human normal immunoglobulin for intramuscular administration (0338)

Human normal immunoglobulin for intravenous administration (0918)

Human normal immunoglobulin for subcutaneous administration (2788)

Human plasma (pooled and treated for virus inactivation) (1646)

Human prothrombin complex (0554)

Human von Willebrand factor (2298)

Kanamycin acid sulfate (0033)

Kanamycin monosulfate monohydrate (0032)

Methylene chloride (0932)

Peritoneal dialysis, solutions for (0862)

Polymyxin B sulfate (0203)

Procainamide hydrochloride (0567)

Propylthiouracil (0525)

Simeticone (1470)

Sodium citrate dihydrate (0412)

Sodium molybdate dihydrate (1565)

Solutions for organ preservation (1264)

Sorafenib tosilate (2931)

Thiamazole (1706)

Zinc acetate dihydrate (1482)

**CORRECTED TEXTS**

*The following texts have been corrected for Supplement 11.8 and specify 'corrected 11.8' above the title. These corrections are to be taken into account as soon as possible and not later than 28 February 2025 (the end of the month following the month of publication of Supplement 11.8).*

**Monographs**

Kaolin, heavy (0503)

Dabigatran etexilate mesilate (3095)

Ethambutol hydrochloride (0553)

**TEXTS WHOSE TITLE HAS CHANGED**

*The titles of the following texts have been changed in Supplement 11.8.*

**MONOGRAPHS**Dicloxacillin sodium monohydrate (0663) (*previously Dicloxacillin sodium*)Doxapram hydrochloride monohydrate (1201) (*previously Doxapram hydrochloride*)Gallium (<sup>68</sup>Ga) chloride (generator-produced) solution for radiolabelling (2464) (*previously Gallium (<sup>68</sup>Ga) chloride solution for radiolabelling*)Kanamycin monosulfate monohydrate (0032) (*previously Kanamycin monosulfate*)Sodium citrate dihydrate (0412) (*previously Sodium citrate*)**SUSPENDED TEXT**

*The following text is suspended as of 1 July 2022.*

**MONOGRAPHS**

Gonadotrophin, equine serum, for veterinary use (0719)

**SUPPRESSED TEXTS**

*The following text is suppressed as of 1 April 2025.*

**GENERAL CHAPTERS**

5.14. Gene transfer medicinal products for human use

*The following text is suppressed as of 1 January 2025.*

**MONOGRAPHS****Vaccines for human use**

Hepatitis A vaccine (inactivated, virosome) (1935)

Influenza vaccine (whole virion, inactivated, prepared in cell cultures) (2308)

**Monographs**

Fluphenazine enantate (1015)

Isoprenaline sulfate (0502)

Phenylmercuric borate (0103)

*The following text is suppressed as of 1 July 2024.*

**MONOGRAPHS**

Hydroxocobalamin sulfate (0915)

*The following text is suppressed as of 1 January 2024.*

**MONOGRAPHS**

Donepezil hydrochloride monohydrate (3067)

*The following texts are suppressed as of 1 July 2023.*

**MONOGRAPHS****Vaccines for human use**

Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)

Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)

Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)

**Monographs**

Ether, anaesthetic (0367)

*The following text is suppressed as of 1 April 2023.*

**MONOGRAPHS**

Diethylstilbestrol (0484)