

Pripomienkovanie článkov Európskeho liekopisu

Štátny ústav pre kontrolu liečiv informuje odbornú verejnosť o možnosti pripomienkovania návrhov nových a revidovaných článkov pred ich zaradením do Európskeho liekopisu.

Aktuálne vydanie Pharmeuropa (36.1) dáva možnosť do 31.3.2024 pripomienkovať

Všeobecné kontrolné metódy a všeobecný text:

2.5.42. N-Nitrosamines in active substances and medicinal products

2.6.7. Mycoplasmas

5.1.9. Guidelines for using the test for sterility

Všeobecné články pre hemodialyzačné, dialyzačné a hemofiltračné roztoky:

Haemodialysis solutions, concentrated, water for diluting/Aqua ad dilutionem solutionum concentratarum ad haemodialysem (1167)

Haemodialysis, concentrated solutions for/Solutiones concentratae ad haemodialysem (3206)

Haemodialysis, solutions for/Solutiones ad haemodialysem (0128)

Haemofiltration and haemodiafiltration, concentrated solutions for/Solutiones concentratae ad haemocolaturam haemodiacolaturamque (2770)

Haemofiltration and haemodiafiltration, solutions for/Solutiones ad haemocolaturam haemodiacolaturamque (0861)

Peritoneal dialysis, solutions for/Solutiones ad peritonealem dialysem (0862)

Monografie:

Aluminium hydroxide, hydrated, for adsorption/Aluminii hydroxidum hydricum ad adsorptionem (1664)

Arachis oil, hydrogenated/Arachidis oleum hydrogenatum (1171)

Clopidogrel hydrogen sulfate/Clopidogreli hydrogenosulfas (2531)

Escitalopram/Escitalopramum (2758)

Escitalopram oxalate/Escitaloprami oxalas (2733)

Esomeprazole magnesium dihydrate/Esomeprazolom magnesticum dihydricum (2787)

Esomeprazole magnesium trihydrate/Esomeprazolom magnesticum trihydricum (2372)

Esomeprazole sodium/Esomeprazolom natricum (2923)

Ethylmorphine hydrochloride dihydrate/Ethylmorphini hydrochloridum dihydricum (0491)

Etodolac/Etodolacum (1422)

Fluconazole/Fluconazolom (2287)

Homatropine hydrobromide/Homatropini hydrobromidum (0500)

Indometacin/Indometacinum (0092)

JK-PSMA-7 (¹⁸F) injection/JK-PSMA-7 (¹⁸F) solutio iniectabilis (3205)

Lacosamide/Lacosamidum (2992)

Lamivudine/Lamivudinum (2217)

Levetiracetam/Levetiracetamum (2535)

Nicotine ditartrate dihydrate/Nicotini ditartras dihydricus (2599)

Nitrendipine/Nitrendininum (1246)

Pregabalin/Pregabalinum (2777)

Remifentanil hydrochloride/Remifentanili hydrochloridum (2644)

Rivaroxaban/Rivaroxabanum (2932)

Ropivacaine hydrochloride monohydrate/Ropivacaini hydrochloridum monohydricum (2335)

Rotigotine/Rotigotinum (3014)

Salicylic acid/Acidum salicylicum (0366)

Sitagliptin phosphate monohydrate/Sitagliptini phosphas monohydricus (2778)

Tapentadol hydrochloride/Tapentadoli hydrochloridum (3035)

Homeopatické prípravky:

Cadmium sulfuricum for homoeopathic preparations/Cadmii sulfas hydricus ad praeparationes homoeopathicas (2143)

Cuprum metallicum for homoeopathic preparations/Cuprum ad praeparationes homoeopathicas (1610)

Ferrum metallicum for homoeopathic preparations/Ferrum ad praeparationes homoeopathicas (2026)

Magnesium phosphoricum for homoeopathic preparations/Magnesii hydrogenophosphas trihydricus ad praeparationes homoeopathicas (2505)

Rastlinné silice, drogy a extrakty:

Cedarwood oil, atlas or himalaya type/Cedri atlanticae vel Cedri deodora ligni aetheroleum (3002)

Clary sage oil/Salviae sclareae aetheroleum (1850)

Clove/Caryophylli flos (0376)

Clove oil/Caryophylli floris aetheroleum (1091)

Liquorice dry extract for flavouring purposes/Liquiritiae extractum siccum ad saporandum (2378)

Liquorice root/Liquiritiae radix (0277)

Očkovacie látky:

Hepatitis A vaccine (inactivated, adsorbed)/Vaccinum hepatitis A inactivatum adsorbatum (1107)

Influenza vaccine (split virion, inactivated)/Vaccinum influenzae inactivatum ex virorum fragmentis praeparatum (0158)

Influenza vaccine (surface antigen, inactivated prepared in cell cultures)/Vaccinum influenzae inactivatum ex cellulis corticisque antigeniis praeparatum (2149)

Influenza vaccine (surface antigen, inactivated, virosome)/Vaccinum influenzae inactivatum ex corticis antigeniis praeparatum virosomale (2053)

Influenza vaccine (surface antigen, inactivated)/Vaccinum influenzae inactivatum ex corticis antigeniis praeparatum (0869)

Influenza vaccine (whole virion, inactivated)/Vaccinum influenzae inactivatum ex viris integris praeparatum (0159)

Poliomyelitis vaccine (inactivated)/Vaccinum poliomyelitidis inactivatum (0214)

Smallpox vaccine (live)/Vaccinum variolae vivum (0164)

Tick-borne encephalitis vaccine (inactivated)/Vaccinum encephalitis ixodibus advectae inactivatum (1375)

Vaccines for veterinary use/Vaccina ad usum veterinarium (0062)

Yellow fever vaccine (live)/Vaccinum febris flavae vivum (0537)

Úplné znenie aj s vyznačením zmien je dostupné na stránke EDQM <https://pharmeuropa.edqm.eu/home> .

Termín pripomienkovania je **do 31. marca 2024**.

Pripomienky posielajte na Liekopisné oddelenie ŠÚKL (ellen.wiesner@sukl.sk), ktoré sprostredkuje ich doručenie do EDQM.