

WAC 246-945-031 Ephedrine prescription restrictions. (1) The commission, under RCW 69.41.075, identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

TRADE NAME	EPHEDRINE CONTENT
1. AMESAC capsule (Russ)	25 mg. ephedrine HCL
2. AZMA AID tablet (Various, e.g., Purepac)	24 mg. ephedrine HCL
3. BRONC-EASE PLUS (Natur-Pharma)	25 mg. ephedrine HCL
4. BRONCHODILATOR AND EXPECTORANT (PDK Labs)	25 mg. ephedrine HCL
5. BRONITIN tablet (Whitehall)	24 mg. ephedrine HCL
6. BRONKAID tablet (Breon)	24 mg. ephedrine sulfate
7. BRONKOLIXER (Sterling Winthrop)	12 mg. ephedrine
8. BRONKOTABS tablet (Breon)	24 mg. ephedrine sulfate
9. EFEDRON nasal jelly (Hyrex)	0.6% ephedrine HCL in 20 g.
10. MINI THINS asthma relief (BDI Pharmaceuticals)	25 mg. ephedrine
11. PAZO HEMORRHOID suppository (Bristol-Meyers)	3.86 mg. ephedrine sulfate
12. PAZO HEMORRHOID ointment (Bristol-Meyers)	0.2% ephedrine sulfate
13. PRIMATENE tablet (Whitehall)	24 mg. ephedrine HCL
14. PRIMATENE M tablet (Whitehall)	24 mg. ephedrine HCL
15. PRIMATENE P tablet (Whitehall)	24 mg. ephedrine HCL
16. QUELIDRINE (Abbott)	5 mg. ephedrine HCL
17. TEDRAL tablet (Parke-Davis)	24 mg. ephedrine HCL
18. THEODRINE tablet (Rugby)	25 mg. ephedrine HCL
19. VATRONOL nose drops (Vicks Health Care)	0.5% ephedrine sulfate

(3) Ma Huang or other botanical products of genus ephedra used in their natural state and containing 25 mg. or less of ephedrine per recommended dosage as a preparation for human consumption are not legend drugs for the purposes of this section.

(4) Any reformulation of listed products which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms shall negate the exemption. The manufacturers of listed products shall notify the commission of any reformulation which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms prior to distributing that product in the state of Washington.

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

(a) Provides the commission with the formulation of any such product;

(b) Provides the commission samples of all dosage forms in which the product is to be marketed in the packaging in which the product is to be marketed; and

(c) Receives the commission's approval to market such product.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-031, filed 6/1/20, effective 7/1/20.]