Pro Pharmaceuticals Group Pty LTD
ABN: 20 605 457 430
www.propg.com.au

Dear Healthcare Professional,

Shortage of NYXOID naloxone hydrochloride dihydrate 2.2 mg/actuation nasal spray vial (AUST R: 309381)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of NYXOID naloxone hydrochloride dihydrate 2.2 mg/actuation nasal spray vial (AUST R: 309381) in Australia.

The Australian registered medicine, NYXOID naloxone hydrochloride dihydrate 2.2 mg/actuation nasal spray vial (AUST R: 309381) is currently in shortage due to an unexpected increase in consumer demand.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **NYXOID naloxone 1.8mg nasal spray solution in a single-dose container (UK)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of *the Therapeutic Goods Act 1989* until ***31st March 2024*** for the following indication(s):

"NYXOID is intended as part of the emergency treatment for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in:

- *the home or other non-medical setting*
- *a health facility setting*

For this reason, NYXOID should be carried by persons at risk of, or likely to witness such events.
NYXOID® is indicated in adults and adolescents aged 14 years and over."

NYXOID naloxone 1.8mg nasal spray solution in a single-dose container (UK) is registered and marketed in UK by Napp Pharma.

Please note that **NYXOID naloxone 1.8mg nasal spray solution in a single-dose container (UK),** is indicated in adults and adolescents aged 14 years and over. This is different to NYXOID® (naloxone hydrochloride dihydrate) 2.2 mg/actuation nasal spray, AUST R 309381, which is indicated in adults and children. However, the quantity, strength, delivered dose, formulation, and device, are the same for these two products.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for the recommended dosing, in line with the above UK indications, and the adverse reaction profile. This is available at: https://www.ebs.tga.gov.au/

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **NYXOID naloxone 1.8mg nasal spray solution in a single-dose container (UK)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at https://www.tga.gov.au/reporting-problems or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints about **NYXOID naloxone 1.8mg nasal spray solution in a single-dose container (UK)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.
For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group