SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

MMOMYELITIS VACCINE TYPE1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 drops = 0.1 ml) contains :

Types 1 attenuated poliomyelitis virus	not less than $10^{6.0}$ $CCID_{50}$
Sucrose	35 %v/v
Erytromycin	not more than 2 mcg
Kanamycin	not more than 10 mcg

3. PHARMACEUTICAL FORM

Clear, light yellow to light red solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

mOPV type 1 is indicated for active immunization against poliomyelitis type1

4.2 Posology and method of administration

Immunization schedule

Monovalent Oral Poliomyelitis Vaccine Type 1 is indicated for poliomyelitis Supplementary Immunization Activities (SIAs) in children from O to 5 years of age. to interrupt type 1 poliovirus transmission in remaining polio endemic areas. The routine poliomyelitis vaccination programme should continue to use trivalent vaccines according to national policy.

Administration

m0PV1 must only be administered orally . Two drops are delivered directly into the mouth from the multi-dose vial by dropper or dispenser.Care should be taken not to contaminate a multi-dose dropper with saliva of the vaccinee.

4.3 Contraindication

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with mOPV1 according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

4.4 Special warnings and precautions for use

In case of diarrhoea, the dose received will not be.counted as part of the immunization schedule aad it should be repeated after recovery.

m0PV1 should not to be used for routine immunization

4.5 Interaction with other medical products and forms of interaction

N/A

4.6 Pregnancy and lactation

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

In the vast majority of cases there are no side effects reported with the trivalent OPV, that includes the same OPV1 component. Very rarely, there may be vaccine-associated paralysis (less than one case per 1 million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

4.9 Overdose

N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N/A

5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Erytromycin
Kanamycin

6.2 Incompatibilities

N/A

6.3 Shelf life

1 years

6.4 Special precautions for storage

Vaccine is potent if stored at not higher than - 20 C until the expiry date indicated on the vial. It can be stored for up to six months between +2 C and +8 C.
The vaccine may present a colour varying from light yellow to light red, due to a slight variation of pH; however this does not affect the quality of the vaccin

6.5 Nature and contents of container

The vaccine comes in vials of 20 doses.

6.6 Special precautions for disposal and other handling

N/A

7. MARKETING AUTHORISATION HOLDER

BioNet-Asia Co.,Ltd.
Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)

1C 10/62 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

March 4, 2019

10. DATE OF REVISION OF THE TEXT