

# SDR-PEP administration

## 1. Purpose

This Standard Operating Procedure (SOP) describes the procedures regarding the administration of single dose rifampicin as post-exposure prophylaxis (SDR-PEP) for leprosy. The SOP helps to protect the rights, safety and welfare of participants.

## 2. Justification

SDR-PEP is advised by the World Health Organization (WHO) in their 2018 [Guidelines on diagnosis, treatment and prevention of leprosy](#) (1).

## 3. Scope

This SOP applies to all aspects of the intervention that involve administration of SDR-PEP to eligible contacts of leprosy index patients.

## 4. Target group

This SOP applies to all health staff involved in the administration of SDR-PEP to eligible contacts of index patients.

## 5. Procedure

All contacts approached for screening and SDR-PEP administration should be documented, including the ones refusing consent (please note the reason for refusal). The administration of SDR-PEP can only start when all aspects of informing and consent giving of the index patient and contacts are fulfilled. For more detail see '[SOP 1: Informing index patients and obtaining their consent](#)' and '[SOP 2: Informing contacts and obtaining their consent](#)'.

### 5.1. Eligibility of contacts to receive SDR-PEP

After obtaining consent from the index patients and contacts, all contacts will have their skin screened. SDR-PEP will only be administered to eligible contacts with negative leprosy and tuberculosis (TB) screening outcomes, or to referred contacts that are followed-up after leprosy/TB are ruled out. Where applicable and feasible, treatment (advice) for other skin diseases may also be provided. For details on eligibility for SDR-PEP refer to '[SOP 3: Eligibility criteria for SDR-PEP and screening of contacts](#)'.

### 5.2. Inform contacts about possible side-effects of SDR-PEP intake

Information on possible side-effects of rifampicin (i.e. flu-like syndrome and temporarily discoloration of body fluids such as urine) should be included in the informed consent form but also needs to be mentioned once more before rifampicin administration. If other or more severe side-effects or adverse events are seen, the contact is advised to seek medical care (for more detail see paragraphs [5.7](#) and [5.8](#) on adverse effects and medications against allergy).

### 5.3. Record all information on contact registration forms

Record all corresponding information of the contact on a designated contact registration form (see the 2020 [WHO Technical Guidance on contact tracing and post-exposure prophylaxis](#) or [Richardus et al.'s practical guide](#) for examples of contact registration forms (2,3)).

#### 5.4. Administration of SDR-PEP

Before SDR-PEP is administered, the expiry date of the rifampicin should be checked. For more information refer to '*SOP 6: Pharmaceutical product procurement and storage: rifampicin and allergy medication*'.

SDR-PEP must be dosed in accordance with the [WHO guidelines](#) (2):

AGE OF CONTACT	DOSE OF RIFAMPICIN
15 years and above	600 mg
10 – 14 years	450 mg
Children 6-9 years (weight ≥20 kg)	300 mg
Children 6-9 years (weight <20 kg)	150 mg
Children 2-5 years and weight ≥10 kg	10-15 mg/kg (liquid form, if available)*

\*If not available, a 150mg capsule for a child in this age-group is often used.

*SDR-PEP administration to young children (≥2yr and ≥10kg):*

- Liquid rifampicin should be given to small children, if available;
- If liquid rifampicin is not available:
  - In case of capsules: break the capsule and dissolve the content in (water/)syrup /juice or put it into a banana;
  - In case of tablets: crush the tablet and dissolve it in (water/) syrup/juice or put it into a banana.

SDR-PEP will be given only in a directly observed way. Do not provide tablets for absent contacts, and use '*SDR-PEP Vouchers*' for pregnant women or children <2 years of age and weighing <10kg (see [5.6](#)).

#### 5.5. 'SDR-PEP Green Card'

Contacts receiving SDR-PEP can also receive a '*SDR-PEP Green Card*'. This card includes (1) a statement that the person has received a single dose rifampicin for leprosy prevention, (2) the date SDR-PEP is provided, and (3) a statement that such person is not eligible to receive SDR-PEP again within 2 years counting from the SDR-PEP administration date. The contacts can save the Green Card in their homes, where it can be kept together with their general medical files.

#### 5.6. 'SDR-PEP Voucher'

Pregnant women and children <2 years of age and/or weighing <10kg are not eligible to receive SDR-PEP. However, with this voucher, they can collect SDR-PEP in a participating local health facility when they have become eligible (after the pregnancy, or in case of young children: after turning 2 years of age and weighing ≥10kg).

#### 5.7. Adverse events following SDR-PEP

Adverse events are unlikely to occur following the administration of a single dose of rifampicin (2). All contacts eligible to receive SDR-PEP should be informed on possible side-effects. Mild flu-like symptoms are the most common side-effect. Another common, harmless and self-limiting side-effect of rifampicin is orange/red discoloration of body-fluids (urine, tears, saliva, faeces, sweat or breast milk). Possible adverse events include fever, skin rashes or liver disease-jaundice (2). The most common side-effects and adverse events are listed in the table below. In case of any adverse event,

the contact should present to the health facility as soon as possible. In addition to the actions described below, any adverse event following SDR-PEP should be reported according to national guidelines of pharmacovigilance.

*Common side-effects/adverse events of rifampicin and action to take*

Side-effect	Action
Orange/red discoloration of urine, tears, saliva, faeces, sweat or breast milk	Reassure patient
Flu-like symptoms	Reassure patient and paracetamol can be prescribed
Adverse event	Action
Allergic reaction (skin rashes with or without itching)	Provide anti-histamine ± steroids and refer immediately for further medical attention. In more severe (and very rare) cases, adrenalin may be needed.
Hepatitis (jaundice)	Refer immediately for further medical attention
Shock (low blood pressure, dizziness or collapse)	Refer immediately for further medical attention

### 5.8. Medication against allergy

It is advised to have at least a few dosages of anti-allergy medication available, including anti-histamine and corticosteroid dosages, in case someone develops an allergic reaction (see '**SOP 6: Pharmaceutical product procurement and storage: rifampicin and allergy medication**'). It could be useful to include these medicines in a separate allergy kit. An allergic reaction is rare after rifampicin, but it is important to always be prepared for allergies for patient safety reasons. Please use the national anti-allergy guidelines (e.g. regarding dosage) when administering anti-allergy medication, monitor the vital functions of the patient and refer the patient quickly if needed.

## 6. Definitions and abbreviations

An overview of all definitions and abbreviations can be found in the document '**Introduction, content and definitions**'.

## 7. Related SOPs and other documents

- SDR-PEP Green Card
- SDR-PEP Voucher
- *SOP 1: Informing index patients and obtaining their consent*
- *SOP 2: Informing contacts and obtaining their consent*
- *SOP 3: Eligibility criteria for SDR-PEP and screening of contacts*
- *SOP 5: Referral of contacts in case of (possible signs or symptoms of) tuberculosis or leprosy*
- *SOP 6: Pharmaceutical product procurement and storage: rifampicin and allergy medication*

## 8. References

1. World Health Organization; Regional Office for South-East Asia. Guidelines for the diagnosis, treatment and prevention of leprosy. 2018.
2. World Health Organization; Regional Office for South-East Asia. Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. Technical guidance. 2020.
3. Richardus JH, Kasang C, Mieras L, Anand S, Bonenberger M, Ignotti E, et al. Minimal essential data to document contact tracing and single dose rifampicin (SDR) for leprosy control in routine settings: a practical guide. *Lepr Rev.* 2018 Mar 1;89(1):2–12.