

IEHK Post exposure prophylaxis (PEP) kit

Product (Material #)	Discontinued:	IEHK2011 PEP kit (S9901003)
	New:	IEHK2016, PEP kit (S9901013)
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Summary

The IEHK PEP kit contains medicines for emergency post-exposure prophylaxis of HIV infection and presumptive treatment of other Sexually Transmitted Infections (STIs) following sexual assault. It also contains emergency contraceptives and pregnancy tests.

The IEHK2011 PEP kit (S9901003) has been discontinued and replaced with IEHK2016, PEP kit (S9901013) based on recent updates to WHO PEP guideline:
<http://www.who.int/hiv/pub/guidelines/en/>

How has the IEHK PEP kit changed?

	IEHK2011 PEP kit (discontinued)	IEHK2016, PEP kit (new)
Drug regimen:	2-drug ARV regimen	3-drug ARV regimen
Adult/child formulations:	PEP medicines for children the same as for adults	PEP medicines for children different from those for adults
Dosage presentation:	ARVs for children provided as single medicines.	Fixed-dose combination (FDC) ARVs for children (i.e., 3-in-1 medicines) are available as dispersible tablets or tablets for oral suspension
Dosage calculation:	ARVs for children are dosed per body weight only.	ARVs for children are dosed by weight and approximate age ranges are provided for use in situations where the child's weight cannot be obtained easily.
Indicative price: (USD)	\$580	\$1,275

Ordering IEHK PEP kit

1. As of January 2017, Supply Division has stopped packing IEHK2011 PEP kit (S9901003).
2. As of December 2016, Supply Division is packing IEHK2016 PEP kit (S9901013).
3. IEHK2016 PEP kit (S9901013) is found in the Supply Catalogue under the subheading “Medical Kits”.
4. Supply Division’s Emergency Supply List (ESL) has been updated to reflect IEHK2016 PEP KIT (S9901013).
5. As of December 2016 sales orders/partner requests should be for IEHK2016 PEP (S9901013).

Important action points for country offices and Procurement Services partners

6. Due to the cost increase of the IEHK PEP kit please plan adequate budgets for your target number of kits.
7. Waivers, exemptions and permits should be arranged well in advance of ordering the kits. This includes:
 - **Intellectual property/patents.** UNICEF has made every effort to seek “non-assert” of intellectual property by the holders. However, in case some of the ARV medicines in this kit have valid intellectual property rights filed in your country, we recommend that the country considers use of TRIPS flexibilities such as “for government use” clause, citing ARV medicines in the kit as emergency supplies. This should be done in advance of ordering the kits to enable importation. See patent status at <http://www.medspal.org/>
 - **Registration.** Supply Division recommends to obtain blanket import waiver for all emergency kits as there may be multiple suppliers for the same product component, and it is not feasible to pre-determine such specificity.
8. Organize a country-based forum to review the information in this technical bulletin and plan to update any relevant country documents. This may include Country Emergency Supply Lists and guidance to health care providers on use of the NEW PEP kit. (See useful information in Annex 1)

Overview of product changes in the IEHK2016 PEP kit (S9901013)

UNICEF material number	Description	Quantity	Remarks
S153101	Azithromycin powder for oral suspension 200 mg / 5 ml, bottle of 15 ml	10	Quantity increased
S1531009	Azithromycin 250 mg scored tablet, blister pack of 6 tablets	34	No change
S1504003	Cefixime powder for oral suspension 100mg/5ml, bottle of 50 ml	10	No change
S1531002	Cefixime 200 mg tablets (as trihydrate), blister pack of 56 tablets	2	No change

UNICEF material number	Description	Quantity	Remarks
S1514130	Levonorgestrel 750 micrograms (mcg) tablets, blister pack of 2 tablets	50	No change
S0584501	HCG urine pregnancy test cassette pack for one test for the qualitative detection of Human Chorionic Gonadotropin (HCG) hormone in urine at the sensitivity of 20 mIU/mL, indicative for pregnancy	50	No change
S1400630	Lamivudine (3TC) 300mg + Tenofovir Disoproxil Fumarate(TDF) 300mg, equivalent to 245mg of Tenofovir Disoproxil, film coated tablets, bottle pack of 30 tablets	50	Added
S1400598	Atazanavir 300mg +Ritonavir 100mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 30 Tablets must be swallowed whole and should not be split, crushed or chewed	50	Added
S1400649	Lamivudine(3TC) 30mg + Zidovudine(AZT) 60mg Fixed Dose Combination (FDC) dispersible tablets, bottle pack of 60 tablets	30	Added
S1400541	Lopinavir 200mg + Ritonavir 50mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 120. Tablets must be swallowed whole and should not be split, crushed or chewed	4	Added
S1400576	Lopinavir 100mg + Ritonavir 25mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 60. Tablets must be swallowed whole and should not be split, crushed or chewed	2	Added
S1400523	3TC150mg+AZT300mg tabs/PAC-60 gb	50	Removed
S1400183	Zidovudine 100mg caps/PAC-100 gb	9	Removed
S1400097	Lamivudine 150mg tab/PAC-60 gb	6	Removed

Sub kits

To facilitate in-country distribution and use, each IEHK2016 PEP kit is composed of “sub kits”: 2 adult “sub kits” and 1 “paediatric sub kit”. Note: Sub-kits cannot be ordered on their own.

Description	Target coverage (per sub kit)	Quantity (sub kits) in each IEHK2016 PEP kit
Adult sub kit	25 adults	2
Paediatric kit	5 children	1

Composition of each adult sub kit:

UNICEF material number	Description	Quantity
S1531009	Azithromycin 250 mg scored tablet, blister pack of 6 tablets	17
S1531002	Cefixime 200 mg tablets (as trihydrate), blister pack of 56 tablets	1
S1514130	Levonorgestrel 750 micrograms (mcg) tablets, blister pack of 2 tablets	25
S0584501	HCG urine pregnancy test cassette pack for one test for the qualitative detection of Human Chorionic Gonadotropin (HCG) hormone in urine at the sensitivity of 20 mIU/ml indicative for pregnancy.	25
S1400630	Lamivudine (3TC) 300mg + Tenofovir Disoproxil Fumarate(TDF) 300mg, equivalent to 245mg of Tenofovir Disoproxil, film coated tablets, bottle pack of 30 tablets.	25
S1400598	**Atazanavir 300mg +Ritonavir 100mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 30 tablets	25

** LPV/r 200+50mg can replace ATV/r 300mg+100mg if there are supply constraints

Composition of each paediatric sub kit

UNICEF material number	Description	Quantity
S1531011	Azithromycin powder for oral suspension 200mg/5ml, bottle of 15ml	10
S1504003	Cefixime powder for oral suspension 100mg/5ml, bottle of 50 ml	10
S1400649	Lamivudine(3TC) 30mg + Zidovudine(AZT) 60mg Fixed Dose Combination (FDC) dispersible tablets, bottle pack of 60 tablets	30
S1400541	Lopinavir 200mg + Ritonavir 50mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 120 tablets Tablets must be swallowed whole and should not be split, crushed, dissolved or chewed	4
S1400576	Lopinavir 100mg + Ritonavir 25mg Fixed Dose Combination (FDC) heat stable tablets, bottle pack of 60 tablets Tablets must be swallowed whole and should not be split, crushed, dissolved or chewed	2

Sample IEHK2016 PEP kit, packed



Weights, dimensions and volumes

- Estimated weight of the master IEHK2016 PEP kit is 21 kg
- Estimated dimensions and volume of the master IEHK2016 PEP kit
 - Double-wall ctn.80x40x50 cm, 0.160 m3
- Estimated weight of each of the sub kits is 7 kg
- Estimated dimensions and volume of each sub kit
 - Double-wall ctn.40x30x25 cm, 0.030 m3

Statement on product quality

- All suppliers are prequalified before being entered in UNICEF supplier database. This involves site visits to confirm Good Manufacturing Practice (GMP).
- All products are technically evaluated and approved by a team of experts in accordance with the WHO Model Quality Assurance System (MQAS) for procurement agencies.
- UNICEF Supply Division is authorized by the Danish Medicines Agency to receive medicinal products from the EU and third countries for the sole purpose of exportation to third countries as part of emergency relief activities in accordance with the Danish Medicines Act no. 1180.
- UNICEF Conforms to all requirements of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.
- UNICEF Has arrangements with independent laboratories to analyse randomly picked samples of medicines purchased for and on behalf of UNICEF.

If you have any queries or comments, please send an email for attention to the Supply Division Medicines and Nutrition Centre at supply@unicef.org.

ANNEX 1

Supplementary information to support the use of IEHK2016 PEP kit contents

This annex provides supplementary information to support the use of IEHK2016 PEP kit contents for:

- Post exposure prophylaxis of HIV
- Presumptive treatment of sexually transmitted infections (STI).
- Prevention of pregnancy

1. Post exposure prophylaxis (PEP) of HIV

For details on WHO recommended Anti-Retroviral (ARV) regimens for post-exposure prophylaxis for HIV infections among adults, adolescents and children, please go to <http://www.who.int/hiv/topics/prophylaxis/en/>
<http://www.who.int/hiv/pub/guidelines/en/>

Rapid diagnostic test kits (RDTs) for HIV are not included in the PEP kit. Testing for HIV is NOT mandatory before offering PEP. Declining an HIV test or non-availability of HIV testing should never be a barrier to initiating PEP. Where testing for HIV is offered before starting PEP, obtain consent to test after explaining the risks and benefits of testing.

Post exposure prophylaxis of HIV should be provided as soon as possible after sexual assault, and within 72 hours. Post-exposure prophylaxis is not indicated if the exposed person is known or confirmed to be HIV positive.

Recommended regimen and dosing for HIV prophylaxis (adults). Lamivudine (3TC) 300mg +Tenofovir (TDF) 300mg fixed dose combination(FDC) tablets, One (1) tablet once daily for 28 days **AND** Atazanavir300mg+ritonavir 100mg (ATV/r) FDC tablets, One (1) tablet once daily for 28 days

Recommended regimen and dosing for HIV prophylaxis for (children). To be administered as per dosing table below for 28 days. Lamivudine (3TC) 30mg+Zidovudine (AZT) 60mg Fixed dose Combination (FDC) dispersible tabs **AND** Lopinavir¹/ritonavir (LPV/r) 100/25mg heat stable tablets **OR** Lopinavir/ritonavir (LPV/r) 200/50mg heat stable tablets.

Weight (kg)		Age	[AZT+3TC] FDC dispersible tablets		Lopinavir/ritonavir (LPV/r) §			
Weight (kg)		Age	Tablet, dispersible 60mg+30 mg	Tablet 100/25 mg	Tablet 200/50 mg			
min	max	Range	am	pm	am	pm	am	pm
3	5.9	0-6months	1	1	NR	NR	NR	NR
6	9.9	6months-1 year	1.5	1.5	NR	NR	NR	NR
10	13.9	1 - 3 years	2	2	2	1	NR	NR
14	19.9	3 - 6 years	2.5	2.5	2	2	1	1
20	24.9	6 - 9 years	3	3	2	2	1	1
25	34.9	9-14 years	4	4	3	3	2	1
35		>14 years	5	5	4	4	2	2

§ LPV/r tablets must be swallowed whole and should not be broken, split, crushed, chewed or dissolved in liquid. These medicines can be taken with or without reference to food.

2. Presumptive treatment of sexually transmitted infections (STIs)

Diagnosis. WHO recommends presumptive treatment of STI in the context of sexual assault or other emergency contexts, especially in areas with high prevalence of STIs. STI diagnosis is not required before offering treatment. The decision to provide presumptive treatment or wait for results of STI tests should be based on assessment of exposure risk and consent of the survivor.

Presumptive treatment. The incubation period of different STIs varies from a few days for gonorrhoea and chancroid to weeks or months for syphilis and HIV.

The STIs covered Presumptive treatment in are those caused by

- Neisseria gonorrhoeae
- Treponema pallidum (syphilis)

Health care provider should offer presumptive treatment for STI after explaining the risks and benefits and obtaining informed consent from the survivor.

STI regimens can start on the same day as emergency contraception and post-exposure prophylaxis for HIV (PEP), although the doses should be spread out (and taken with food) to reduce side-effects, such as nausea.

Recommended regimen and dosing for presumptive STI treatment (adolescents and adults).

Single dose Azithromycin 1g orally AND Single dose Cefixime 400 mg orally

Recommended regimen and dosing for presumptive STI treatment (children). Single dose Azithromycin 20 mg/kg orally AND Single dose Cefixime 8 mg / kg orally.

3. Prevention of pregnancy

Pregnancy test kit is included in the PEP kit. Testing for pregnancy is not mandatory before offering emergency contraception. However, pregnancy risk assessment and medical eligibility criteria for using emergency contraception should be conducted before offering emergency contraception.

Levonorgestrel, the emergency contraceptive in the IEHK PEP kit has label claim to be effective up to 72 hours (3 days) after unprotected sexual intercourse. Although it has demonstrated effectiveness up to 96 hours (4 days), effectiveness beyond 72 hours is outside the product license. Levonorgestrel should be taken as a single dose (1.5 mg) or alternatively, in 2 doses (0.75 mg each, 12 hours apart). Evidence indicates that it prevents pregnancy in 52–94% of situations.