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Appendix - FIRST-LINE DRUGS FOR HIV POSTEXPOSURE PROPHYLAXIS (PEP)

Nucleoside Reverse Transcriptase Inhibitors

Zidovudine (RETROVIR(R); ZDV, AZT)

Dosage: 600 mg every day in divided doses (e.g., 300 mg twice a day, 200 mg three times a day, or 100 mg every four hours).

Primary toxicities and/or side effects: Neutropenia, anemia, nausea, fatigue, malaise, headache, insomnia, and asthenia.

Comments: Caution should be used if co-administered with bone marrow suppressive drugs or cytotoxic therapy.

Lamivudine (EPIVIR(TM); 3TC)

Dosage: 150 mg twice a day.

Primary toxicities and/or side effects: Headache, abdominal pain, diarrhea, and in rare cases, pancreatitis. Toxicity of ZDV and 3TC when used in combination is approximately equal to that of ZDV alone.

ZDV plus 3TC (COMBIVIR(TM))

Dosage: 1 tablet twice a day; each tablet contains 300 mg ZDV and 150 mg 3TC.

Primary toxicities and/or side effects: See above for ZDV and 3TC.

Comments: Caution should be used if co-administered with bone marrow suppressive drugs or cytotoxic therapy.

Protease Inhibitors (PIs) **

Indinavir (CRIXIVAN(R); IDV)

Dosage: 800 mg every 8 hours on an empty stomach (i.e., without food or with a light meal).

Primary toxicities and/or side effects: Nephrolithiasis, crystalluria, hematuria, nausea, headache, indirect

hyperbilirubinemia, elevated liver function tests (LFTs), and hyperglycemia/diabetes.

Primary drug interactions ***: No PI should be co-administered with terfenadine (Seldane(R)), astemizole (Hismanal(R)), cisapride (Propulsid(R)), triazolam, and midazolam. Rifampin should not be administered with PIs. Cytochrome P450 metabolism inhibitors like ketoconazole may increase PI plasma concentrations; dose reduction of the PI is only indicated for indinavir. Ergot alkaloid preparations should not be used in combination with PIs. If rifabutin is used concomitantly, rifabutin dose should be reduced because of inhibition of rifabutin metabolism; with concomitant indinavir or nelfinavir use, reduce rifabutin dose by 50%.: Serum levels of PIs may be increased when multiple PIs are used in combination.

Comments: Incidence of nephrolithiasis may be reduced by consuming large quantities of water (i.e., drinking six 8 oz glasses of water {total 48 oz} throughout the day).

Nelfinavir (VIRACEPT(TM))

Dosage: 750 mg three times a day (with meals or a light snack).

Primary toxicities and/or side effects: Diarrhea and hyperglycemia/diabetes.

Primary drug interactions ***: See above for indinavir.

Comments: Diarrhea usually can be controlled with over-the-counter antidiarrheal drugs (e.g., loperamide).: If oral contraceptives are being used, alternative or additional contraceptive measures should be used while taking nelfinavir.

ANTIRETROVIRAL DRUGS USED FOR TREATMENT OF HIV INFECTION THAT MAY BE CONSIDERED FOR PEP IN SPECIAL CIRCUMSTANCES

Nucleoside Reverse Transcriptase Inhibitors

Zalcitabine (HIVID(R), ddC)

Dosage: 0.75 mg every 8 hours.

Primary toxicities and/or side effects: Stomatitis and peripheral neuropathy.

Primary drug interactions ***: Do not co-administer ddC with didanosine or stavudine because of the potential for enhanced peripheral neuropathy.

Comments: Peripheral neuropathy from ddC is usually after prolonged exposure.

Didanosine (VIDEX(R), ddI)

Dosage: 200 mg twice a day; if body weight is less than 60 kg, 125 mg twice a day. Should be taken on an empty stomach.

Primary toxicities and/or side effects: Pancreatitis, peripheral neuropathy, nausea, and diarrhea.

Primary drug interactions ***: Do not co-administer ddI with ddC because of the potential for enhanced peripheral neuropathy.

Comments: Peripheral neuropathy from ddI is usually after prolonged exposure.: To avoid potential drug interactions, give concomitant medications 2 hours after ddI dosing.

Stavudine (ZERIT(TM), d4T)

Dosage: 40 mg twice a day; if body weight is less than 60 kg, 30 mg twice a day.

Primary toxicities and/or side effects: Peripheral neuropathy.

Primary drug interactions ***: Do not co-administer d4T with ddC because of the potential for enhanced peripheral neuropathy.

Comments: Peripheral neuropathy from d4T is usually after prolonged exposure.

Protease Inhibitors (PIs) **

Ritonavir (NORVIR(TM))

Dosage: 600 mg twice a day; dose escalation recommended (300 mg twice a day for 1 day, 400 mg twice a day for 2 days, 500 mg twice a day for 1 day, then 600 mg twice a day for duration of regimen).

Primary toxicities and/or side effects: Nausea, emesis, diarrhea, circumoral paresthesia, taste alteration, increased cholesterol and triglycerides, hyperglycemia/diabetes, and increased LFTs.

Primary drug interactions ***: No PI should be co-administered with terfenadine (Seldane(R)), astemizole (Hismanal(R)), cisapride (Propulsid(R)), triazolam, or midazolam. Rifampin should not be administered with PIs. Cytochrome P450 metabolism inhibitors such as ketoconazole may increase protease inhibitor plasma concentrations. Ergot alkaloid preparations should not be used in combination with PIs. Rifabutin should not be co-administered with either saquinavir (because of reduction of saquinavir serum concentrations) or ritonavir (because of increased rifabutin concentrations).: Serum levels of PIs may be increased when multiple PIs are used in combination.

Comments: Ritonavir should not be used with various antiarrhythmics and certain sedatives or hypnotics. Ritonavir also has potential interactions with certain analgesics, antibiotics, antidepressants, anti-emetics, antifungals, calcium channel blockers, and other medications.: If oral contraceptives are being used, alternative or additional contraceptive measures should be used while taking ritonavir.

Saquinavir (INVIRASE(TM), hard-gel formulation) (FORTOVASE(TM), soft-gel formulation)

Dosage: INVIRASE, 600 mg three times a day with fatty meals; FORTOVASE, 1200 mg three times a day within 2 hours of a meal. (If saquinavir is used for PEP, Fortovase should be used.)

Primary toxicities and/or side effects: Diarrhea, headache, hyperglycemia/diabetes, and increased LFTs and triglycerides.

Primary drug interactions ***: See above for ritonavir.

Non-nucleoside Reverse Transcriptase Inhibitors

Nevirapine (VIRAMUNE(R))

Dosage: 200 mg once a day for the first 2 weeks then 200 mg twice a day.

Primary toxicities and/or side effects: Rash (including rare cases of Stevens-Johnson syndrome), fever, nausea, headache, and increased LFTs.

Primary drug interactions ***: Nevirapine induces hepatic cytochrome CYP3A isoforms; however, drug interaction studies with drugs metabolized by this enzyme have not been conducted. Careful monitoring is therefore recommended if nevirapine is co-administered with other drugs metabolized by this route because decreased serum concentrations (and decreased effectiveness) of the other drugs may be observed (e.g., oral contraceptives, rifampin, and rifabutin). Use of nevirapine may decrease levels of indinavir or saquinavir.: This drug should only be used in combination with other antiretroviral drugs.

Comments: Oral contraceptives may be less effective during concomitant use with nevirapine.

Delavirdine (RESCRIPTOR(R))

Dosage: 400 mg three times a day

Primary toxicities and/or side effects: Rash (including rare cases of Stevens-Johnson syndrome), nausea, and increased LFTs.

Primary drug interactions ***: Delavirdine inhibits hepatic cytochrome CYP3A isoforms. Should not be coadministered with terfenadine (Seldane(R)), astemizole (Hismanal(R)), cisapride (Propulsid(R)), triazolam, midazolam, nifedipine, anticonvulsants, amphetamines, rifabutin, or rifampin. Delavirdine may increase PI levels.: This drug should only be used in combination with other antiretroviral drugs.

Comments: Antacids and ddI decrease absorption of delavirdine and should be taken 2 hours apart.

- Information included in these recommendations may not represent Food and Drug Administration (FDA) approval or approved labeling for the particular products or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

** It is recommended that consultation with experts in the treatment of HIV infection and disease be sought when considering the inclusion of PIs or the use of alternative agents in PEP regimens.

*** See package insert for other contraindications and possible drug interactions.

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