

DIVISION OF STRATEGIC NATIONAL STOCKPILE



Formulary



Division of Strategic National Stockpile (SNS)

SNS FORMULARY



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CENTERS FOR DISEASE CONTROL & PREVENTION



Objectives

- **Formulary Selection Process**
- **Stockpile Items**
- **Labeling**
- **Investigational New Drug/Emergency Use Authorization**



Selecting Items for the Stockpile

- Intra-governmental Committee meetings
- Working Group Involvement
- REASON



R-E-A-S-O-N

- R=rotation capability
- E=effectiveness of the drug against agents
- A=availability of the drug
- S=storage consideration
- O=other considerations
- N=need for ancillary supplies



What's In the Stockpile?



- Medical/Surgical Supplies
- Equipment
- Pharmaceuticals





Person in a blue Superman shirt and white pants standing on the carts.

CDC 3102 SP

CDC 3108 SP

CDC 1517 SP

CDC 1463 SP

Baxter
Baxter
Baxter
Baxter
Baxter
Baxter
TARE WT
101 LBS
182 KGS

Baxter
Baxter
Baxter
Baxter
Baxter
Baxter
TARE WT
203 LBS
182 KGS

Baxter
Baxter
Baxter
Baxter
Baxter
Baxter
TARE WT
203 LBS
182 KGS

Baxter
Baxter
Baxter
Baxter
Baxter
Baxter
TARE WT
101 LBS
182 KGS

105

116

085

011

Medical / Surgical Supplies

➤ IV administration supplies



- ✓ Sterile Water for Injection
- ✓ NaCl flush
- ✓ Syringes/needles/catheters
- ✓ Heparin Locks
- ✓ Y site administration sets
- ✓ IV solutions (1000ml/100ml)
- ✓ Gloves
- ✓ Tape/ dressings/ gauze/ tourniquets
- ✓ Alcohol pads, betadine swabs, antibiotic ointment



Medical / Surgical Supplies

➤ Airway Supplies



- ✓ ET tubes/ stylettes
- ✓ NG tubes
- ✓ Oropharyngeal airways
- ✓ Laryngoscopes
- ✓ Oxygen masks/ tubing
- ✓ Manual resuscitators (bag-mask-valve)/ CO₂ detectors
- ✓ Pediatric and adult sizes where applicable



Pediatric Container



- Broselow Tape
- Suction Catheters
- Nasogastric Tubes
- Endotracheal Tubes, Stylettes and Laryngoscopes
- Oropharyngeal airways
- AMBU bags
- Non-rebreather masks
- IV catheters, 24 g
- Oral dosing syringes



Equipment

➤ Ventilators (VMI)



➤ Suction Units (VMI)



Pharmaceuticals

- Antibiotics
- Chemical Nerve agent antidotes
- Other emergency medications
- Vaccines, antitoxins, antivirals



Pharmaceuticals - Antibiotics



- Doxycycline
- Ciprofloxacin
- Gentamicin
- Amoxicillin
- Rifampin, PCN, Vancomycin, Clindamycin, Levaquin



Doxycycline

➤ Uses:

- ✓ Inhalation Anthrax*
- ✓ Plague*
- ✓ Tularemia*

*FDA approved for treatment and prophylaxis

➤ Dosage Forms:

- ✓ IV (100mg powder vial)
- ✓ PO (100mg tablets unit-of-use; 25mg/5ml, 60 ml suspension)



Ciprofloxacin

➤ Uses:

- ✓ Inhalation Anthrax
(approved tx/prophy)
- ✓ Tularemia
(IND tx/prophy)
- ✓ Plague
(IND prophy)

➤ Dosage Forms:

- ✓ IV (400mg in D5W, 200ml bag)
- ✓ PO (500mg tablets unit of use, 250mg/5ml, 100ml suspension – diluent included)



Gentamicin

➤ Uses:

- ✓ Plague*
- ✓ Tularemia*

➤ Dosage Forms:

- ✓ IV/IM (40mg/ml 20ml multi-dose vial)

***IND for treatment**



Amoxicillin

➤ Uses:

✓ Inhalation Anthrax

- Post-exposure prophylaxis*

➤ Dosage Forms:

✓ Oral:

- *500mg capsules
unit of use;
400mg/5ml
suspension*



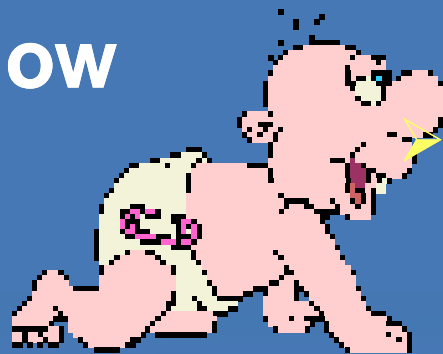


No cats were actually injured during the creation of this PowerPoint presentation!



Pediatric Drug Forms

- Managed Inventory contains ciprofloxacin, doxycycline and amoxicillin oral liquids for children and adults who cannot swallow whole tabs
- Back up: Crush doxy pills (FDA website)
- Compound oral suspensions from doxycycline or Ciprofloxacin tabs (V9; Appendix M)



Pediatric Issues

- Suspensions removed from 12-hour Push Packages
- Consolidated in several locations
- Can ship suspensions in the same time frame as 12-hour Push Package if needed
 - ✓ Adhere to 12 hour time frame
- Allows for better response to an event
 - ✓ Maximizes ability to deliver available suspension



Pediatric Issues

- Current operating plan if suspension is needed:
 - ✓ 25% of available doxycycline will be shipped during an event
 - ✓ Ciprofloxacin and amoxicillin suspensions will be shipped in an amount equal to what was in one 12-hour Push Package



Pharmaceuticals: Chemical Nerve Agent Antidotes

- Atropine
- Pralidoxime
- Diazepam



Atropine

➤ Uses:

- ✓ Nerve agents/organophosphates

➤ Dosage Forms:

- ✓ IV (*0.4mg/ml 20 ml vial*)
- ✓ Autoinjector (Mark 1 kit)
 - 2mg atropine



Pralidoxime (2-PAM)

- **Uses:**
 - ✓ Nerve agents/organophosphates
- **Dosage Forms:**
 - ✓ IV (1 gram powder vial)
 - ✓ Autoinjector (Mark 1 kit)
 - 600mg pralidoxime



Diazepam

- Uses:
 - ✓ Nerve agents/organophosphates
- Dosage Forms:
 - ✓ IV (*5mg/ml, 10ml vial*)
 - ✓ Autoinjector
 - 10mg diazepam



Controlled Substances



- Morphine C-II
- Diazepam C-IV
- Midazolam C-IV
- Special DEA Considerations:
 - ✓ Shipping
 - ✓ Receiving
 - ✓ Distributing
 - ✓ Dispensing



Other Emergency Medications

- Dopamine
- Epinephrine/Epi-Pens
- Methylprednisolone
- Albuterol Inhaler



Radiation and Burn/Blast

➤ Items for Radiation

Prussian Blue, Ca and Zn-DTPA, Neupogen,
Nausea & Pain medications

➤ Items for Burn and Blast

Bacitracin, Silvadene, IV fluids, Wound care items



Vaccines and Related Supplies

- **Smallpox vaccine**
 - ✓ **Wyeth Dryvax (1:1 FDA approved; 1:5 IND)**
 - ✓ **Aventis Pasteur (IND)**
 - ✓ **ACAM 2000 (IND)**
 - ✓ **Diluent**
 - ✓ **Bifurcated needles**
- **Anthrax vaccine (FDA approved for pre-exposure; IND for post-exposure)**
- **Other: cidofovir/VIG (both IND)**



Antitoxin and Antivirals

➤ Antitoxin

- ✓ Botulinum

➤ Antiviral

- ✓ Tamiflu (capsules, suspension)
- ✓ Rimantadine (tablets, syrup)
- ✓ Relenza (inhaler)
- ✓ Cidofovir (for smallpox)



Required Documentation

- Patient Information sheets, provider information sheets
- Controlled Substances
- IND/consent forms





Labeling



Labeling Issues

- FDA required data
 - ✓ Drug, strength, quantity
 - ✓ Name of patient*
 - ✓ Directions for use*
 - ✓ Cautionary statements*
 - ✓ Name/address of dispenser
 - ✓ Serial number & date of RX (or of it's filling)
 - ✓ Name of prescriber



** If stated in the RX*



Labeling Issues

- Type of label determines additional data required (see V-10, Appendix O)
 - ✓ Unit-of-use bottles (Drug name, strength, lot, prescription #)

DRUGStore
WADALAND PHARMACY LTD.
2431 TRAFALGAR RD.
OAKVILLE ON (905) 257-4142

Rx: LON123456 01/01/01
SMITH, JOHN rep: 0
TYLENOL WITH COCAINE #3
40 TAB ONC DR. DOE, J.
TAKE 2 TABLETS EVERY 4
HOURS AS REQUIRED



SNS Labels

1) Original

- ✓ *doxy, cipro, amoxicillin*

2) One time Purchase

- ✓ *doxy*

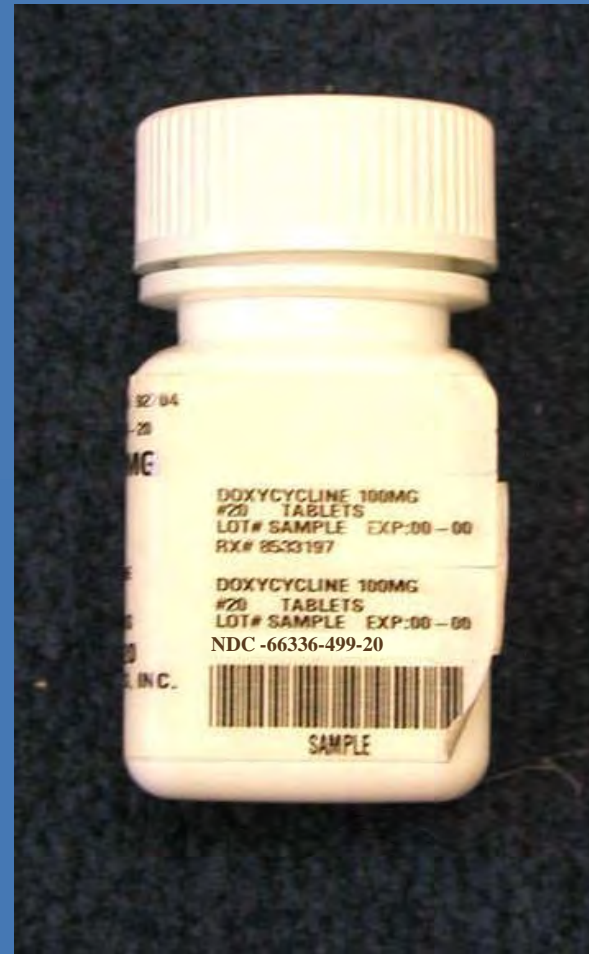
3) Future labels

- ✓ *doxy, cipro, amoxicillin*

4) Shelf Life Extension Program (SLEP) labels



Unit of Use Bottles - Original



Tabs on side – may be removed and used for patient tracking



Unit of Use Bottles - Ivax



**NDC 1111-3535-22
Doxycycline Hyclate
Tablets USP, 100mg
Lot: 333444**

Above stickers are provided and may be removed and used for patient tracking



Upcoming Bottles

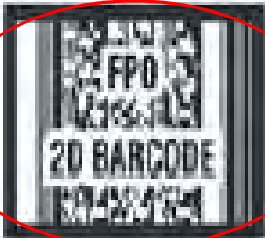
- Standard labeling
- Pull off tabs:
 - ✓ Drug name, strength, qty, lot, Rx, NDC, expiration date
- Bar code
 - ✓ Rx number
 - ✓ NDC/Lot number (2D)



New Labels

PACKAGED BY DISPENSING SOLUTIONS, INC.
SANTA ANA, CA 92704
MANUFACTURED BY IVAX PHARMACEUTICALS, INC.
MIAMI, FL 33137

NDC 68336-449-20



STORE AT 20°-25°C (68°-77°F)
[SEE USP CONTROLLED ROOM TEMPERATURE].

FOR STRATEGIC NATIONAL
STOCKPILE USE ONLY

DOXYCYCLINE 100 mg


EACH TABLET CONTAINS:
DOXYCYCLINE HYCLATE
EQUIVALENT TO DOXYCYCLINE
100 mg, FD&C YELLOW #6.

20 TABLETS

**USUAL DOSAGE: Take one
tablet every 12 hours.**

RX ONLY

LOT# S01330 EXP: Sep-07
RX# 1000000001 (999-9999)



DOXYCYCLINE 100 mg
20 TABLETS
LOT# S01330 EXP: Sep-07
RX# 1000000001
NDC 68336-449-20

DOXYCYCLINE 100 mg
20 TABLETS
LOT# S01330 EXP: Sep-07
RX# 1000000001
NDC 68336-449-20

KEEP OUT OF THE REACH OF CHILDREN
DISPENSE IN THIS TIGHT, LIGHT
RESISTANT CONTAINER



SLEP Labels

PACKAGED BY **PARACELMUS CALIFORNIA, INC.**
10000000001

MANUFACTURED BY **PARACELMUS CALIFORNIA, INC.**
10000000001

**EXPIRATION DATE EXTENDED
PURSUANT TO FDA SHELF LIFE
EXTENSION PROGRAM TO:
EXP: Jun-05**

NDC 66336-449-20

FOR STRATEGIC NATIONAL
STOCKPILE USE ONLY

DOXYCYCLINE 100 mg

EACH TABLET CONTAINS:
DOXYCYCLINE HYCLATE
EQUIVALENT TO DOXYCYCLINE
100 mg, FD&C YELLOW #6

20 TABLETS

USUAL DOSAGE: Take one
tablet every 12 hours

RX ONLY

LOT# 512534 EXP: Jun-05
RX# 1000000001

DOXYCYCLINE 100 mg
20 TABLETS
LOT# 512534 EXP: Jun-05
RX# 1000000001
NDC 66336-449-20

DOXYCYCLINE 100 mg
20 TABLETS
LOT# 512534 EXP: Jun-05
RX# 1000000001
NDC 66336-449-20

STORE AT 20°-25°C (68°-77°F)
(SEE USP CONTROLLED ROOM TEMPERATURE)

KEEP OUT OF THE REACH OF CHILDREN
DISPENSE IN THIS TIGHT/LIGHT
RESISTANT CONTAINER



Tracking Stickers

Original Labels

**Doxycycline 100mg
20 Tablets
Lot: 334 EXP: May 05
RX: 123456 (or NDC)**

IVAX Label (VMI)

**Doxycycline 100mg
20 Tablets
Lot: 334 EXP: May 05
NDC 1111-3535-22**

New Labels

**Doxycycline 100mg
20 Tablets
Lot: 334 EXP: May 05
NDC 1111-3535-22
RX: 123456**

SLEP Labels

**Doxycycline 100mg
20 Tablets
Lot: 334 EXP: May 05
NDC 1111-3535-22
RX: 123456**





Questions / Comments



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