



SAFE USE

collaborating to reduce preventable harm
from medications

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The vast majority of harm from approved drugs occurs because of suboptimal use including: misuse, inappropriate use, failure to use and medical mix-ups and these are preventable



Safe Use Initiative

- ❖ Complements the regulatory authority of the Center
- ❖ Focused externally activities within healthcare community - those who prescribe, dispense, administer and use prescription and over the counter drugs
- ❖ FDA collaborate and partner with those involved to positively influence the safe use of OTC and prescription drugs to reduce preventable harm



Goals of the Safe Use Initiative

- ❖ To create long lasting public and private partnerships within the healthcare community in order to influence and encourage safe medication use through coordinated efforts
- ❖ To have an increased national awareness of how to safely use prescription and OTC medications thus reducing preventable harm and creating a healthier nation
- ❖ To develop true and reliable measures of the success of Safe Use through collaborations and partnerships within the healthcare community in increasing safe medication use and decreasing preventable harm

Achieving the Goals of Safe Use

- ❖ Identify CDER regulated products that appear to be implicated in unsafe medication practices and identify areas in which unsafe medication practices occur
- ❖ Partnerships and coordinated efforts with public and private healthcare organizations
 - ❖ Gather information regarding unsafe use of identified regulated products and or areas of unsafe use
 - ❖ Influence safe use through a unified approach with outreach, education and support networks
 - ❖ Develop measures to determine how well the safe use message is being heard and understood



Reaching out to Partners

Thinking Globally

- ❖ Federal Agencies --
- ❖ Professional Societies -- Physicians, Nurses, Pharmacists.....
- ❖ Healthcare Safety Organizations --
- ❖ Organizations for Consumers --
- ❖ Payer Organizations --
- ❖ Accrediting, and or Standard Setting Groups --
- ❖ Others



Reaching out to Partners

But Starting Locally

❖ **FDA**

- ❖ Review Divisions
- ❖ Office of Special Health Issues
- ❖ Drug Safety Oversight Board
- ❖ Office of Communications
- ❖ Other Centers
- ❖ Pediatric and Maternal Health Staff
- ❖ Office of Women's Health
- ❖ Public Affairs Specialists (PAS)

Safe Use Projects

Sources for Safe Use Projects

- ❖ Research of Literature, Databases and News Sources
- ❖ Discussions with CDER Director, CDER DSB, Review divisions and Staff
- ❖ **Listening sessions with public agencies and private organizations involved in healthcare and public health**
- ❖ **Larger public meeting**
- ❖ **Submissions to Safe Use Docket at [Regulations.gov](https://www.regulations.gov)**

Safe Use Projects

Reasons for Choice of Potential Projects

- ❖ FDA regulated product, therapeutic class of products or potentially a therapeutic area that demonstrates public health and public safety issues
 - ❖ Population based data provides support for intervention and action
 - ❖ Actions and activities would be within the scope of safe use (could not be handled within the regulatory purview of FDA or another agency)
 - ❖ Impact of actions can be measured/quantified
 - ❖ High risk of preventable harm or serious preventable harm
 - ❖ Concern within the public and healthcare community and willingness and interest to work towards resolving



Safe Use Projects

Acetaminophen

- ❖ Non-prescription (OTC) and Prescription
 - ❖ Risks of taking more than recommended dose – Liver damage
 - ❖ One of the main reasons for liver transplant
 - ❖ Overdoses can cause organ failure and death
 - ❖ Regulatory actions are happening – lots of activity



Safe Use Projects

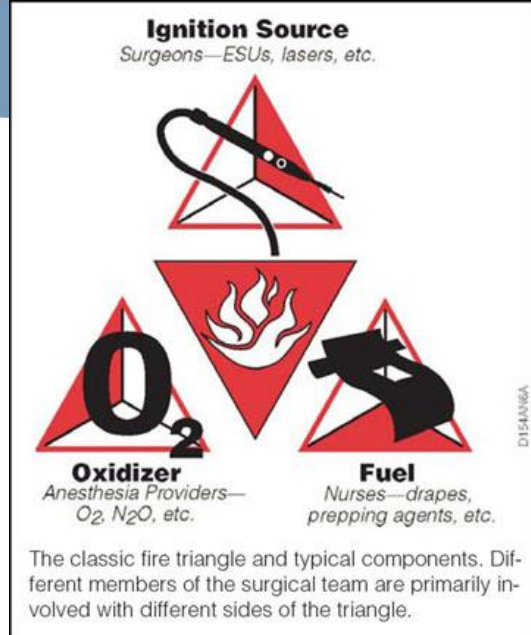
Acetaminophen

- ❖ Safe Use Role
- ❖ Beyond the regulatory actions
 - ❖ Bridge the information gap - Partner with healthcare professionals, healthcare organizations, and consumer groups to enhance
 - ❖ Awareness of what drugs have acetaminophen, APAP, paracetamol
 - ❖ Understanding of the harm if used improperly

Safe Use Projects

Alcohol Based Skin Preps

- ❖ Cleansing skin prior to surgery
- ❖ Risks of Surgical Fire (100-600/year)
 - ❖ Electrocautery device used (Spark)
 - ❖ Alcohol containing Skin prep (Fuel)
 - ❖ Oxygen (Oxidizer)





DuraPrep 26 mL

Drug Facts

Active ingredients

Iodine povacrylex (0.7% available iodine)
Isopropyl alcohol, 74% w/w

Purpose

Antiseptic
Antiseptic

Uses

patient preoperative skin preparation: • for preparation of the skin prior to surgery
• helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce the risk of fire

- do not use 26-mL applicator for head and neck surgery
- do not use on an area smaller than 8 in. x 10 in. Use a small applicator instead.
- solution contains alcohol and gives off **flammable vapors**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
- do not allow solution to pool
- remove solution-stained material from prep area



Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- In infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

When using this product

- keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain. If contact occurs, flush with cold water right away and contact a doctor.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc... applied over film
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions (follow all directions for use)

- at the end of the prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount; available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:

- with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- wait for fluid level to reach indicator line of applicator barrel

When Applying Solution:

- DO NOT SCRUB.** Paint a single, uniform application and do not reprep area.
- do not allow solution to pool.** Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze.
- clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.)
- tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- avoid getting solution into hairy areas. If this occurs, wipe hair with towel. Solution may take much longer to dry or may not dry completely.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.



After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry (minimum of 3 minutes on hairless skin).** Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.



After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed
- if incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film.
- apply dressing following standard practices

Other information • store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients ethyl alcohol, water

Questions? call 1-800-228-3957 (Monday to Friday 7AM - 6PM CST). www.3M.com.

Safe Use Projects

Alcohol Based Skin Preps

- ❖ Determine what information would prevent fires and harm to the patient
- ❖ Determine what methods would prevent fires and harm to the patient
- ❖ Discussions with CDRH
- ❖ External contact and discussion with external stakeholders

Safe Use

Where are we now

- ❖ Beginning –
 - ❖ Nov 4, 2009, rolled out the safe use initiative
 - ❖ Document and Website
 - ❖ Docket opened for comments - <http://www.regulations.gov>
- ❖ Starting with pilot projects and gathering data
- ❖ Connecting and Collaborating with federal partners
- ❖ Gaining contacts and initiating listening sessions with healthcare organizations/stakeholders to understand their safe use concerns
- ❖ Planning larger healthcare public meeting to occur in 2010