

LABELLING OF THE DISPENSED MEDICINES



After dispensing the medicine in a container, a label is attached by adhesive. The label on the dispensed medicines should provide the following information:—

1. Name of the preparation-

When the prescriber mentions the name in the prescription the same name must be displayed on the label.

Eg:

PIPERAZINE CITRATE ELIXIR IP

If it is a non-official preparation then the name of the dosage form should be given on the label.

e.g. THE MIXTURE, THE EMULSION, THE DUSTING POWDER

Cont...

2. The strength of the medicine-

The strength of the active ingredient in the preparation must be displayed if it is intended for internal (oral) purpose. The amount in each unit of dose should be mentioned.

e.g. In case of oral liquids “Each 5ml contains 250mg”

e.g. In case of tablet “Each tablet contains 500mg”.

Cont...

The values must be written in whole numbers and if decimal is not avoidable then a zero is placed before the decimal point

.E.g. instead of 0.1g it should be 100mg, and instead of .5% it should be 0.5%. In case of an official preparation the strength is not required to be given, because the name with reference to the pharmacopoeia is sufficient.

E.g. CHLORAMPHENICOL ORAL SUSPENSION
IP.

INTRODUCTION

- Label means display of printed information which is securely affixed to the containers and primary packaging containing the medicines.
- Label should provide the patient with all necessary information for appropriate use of medicine
 - General labeling requirements
 - Cautionary and advisory labels
 - Special instructions for different types of products

Properties of Label

➤ Information given on label should be;

- Accurate
- Legible
- Intelligible(able to understand)
- Adequate and relevant



Importance of Label

- To provide consumers with information on the product
- To ensure the appropriate and safe use of approved products
- To distinguish the product from that of competitors (establish a brand)
- A legal requirement.

General labeling requirements for dispensed medications

- The name of preparation
- The quantity
- Instructions for the patient
- The patient name
- The date of dispensing
- The name and address of pharmacy

	Brand name	Strength	Price (concession rate plus price premium)
Number of tablets	30 ZOCOR TABLETS 10mg		\$5.38
Active ingredient	[Simvastatin]		
Instructions	Take ONE tablet with a glass of water ONCE a day.		
Special instructions or warnings	Avoid eating grapefruit or drinking grapefruit juice.		
Patient's name	Mr A Confos		
Doctor who prescribed medicine	Dr D Thorpe		
Date medicine was dispensed	20/08/2006		
	KEEP OUT OF REACH OF CHILDREN		
	DOWNTOWN PHARMACY 84 Brisbane St, Perth WA 7000 Tel 08 9585 6333		
	Pharmacy that dispensed medicine		

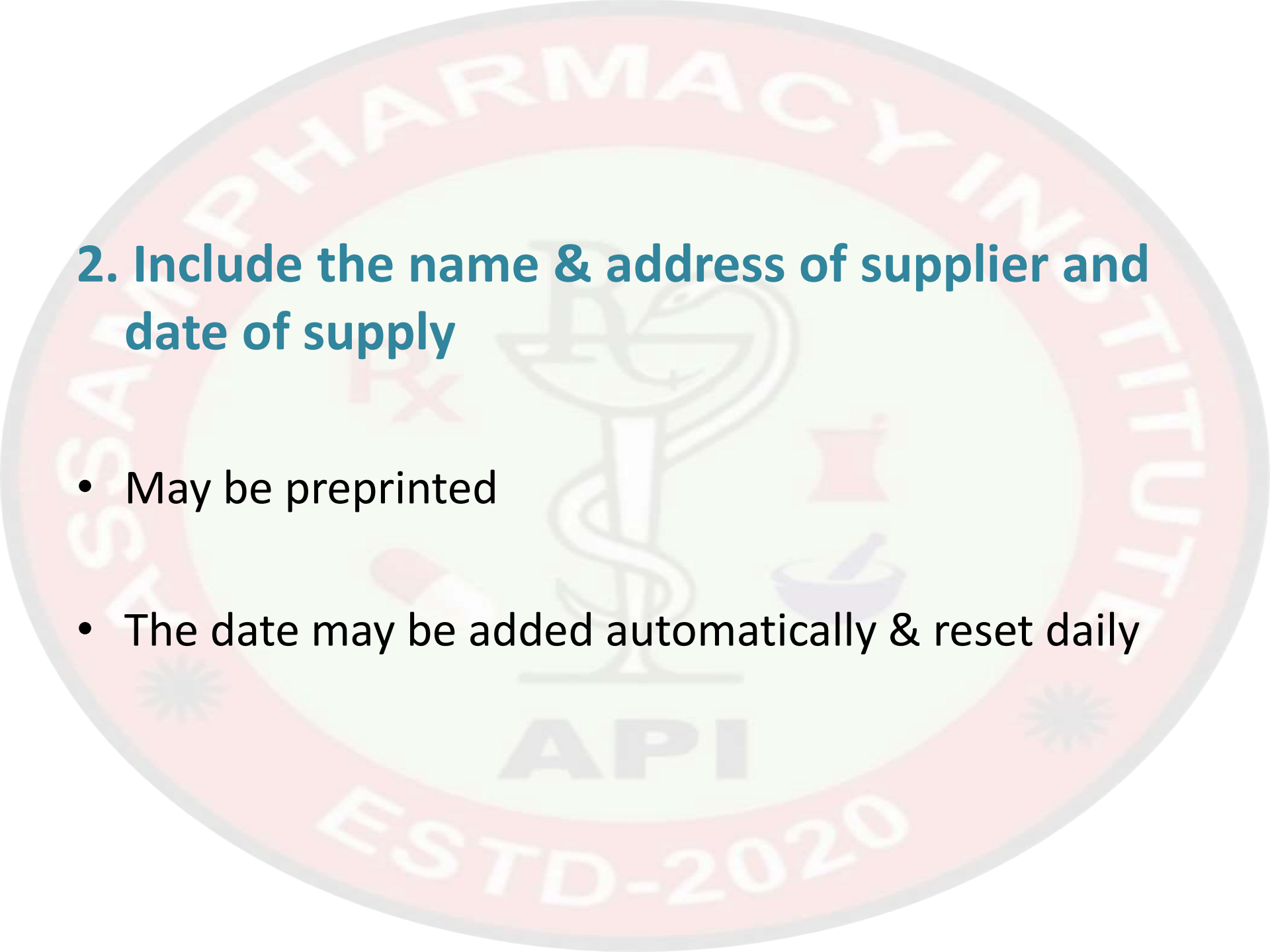
GENERAL LABELING REQUIREMENTS



Information on the Label

1. Indicate clearly the patient for whom it has been prescribed

- Patient's title
 - First Name
 - Surname



2. Include the name & address of supplier and date of supply

- May be preprinted
- The date may be added automatically & reset daily

3. Give precise details as the contents of the container

- **The quantity in the container**
- **The name of medicine**
 - Brand or non-proprietary name
 - Labeled by pharmaceutical form (special formula)
(The Tablets, The Sedative Tablets)

- **The strength of the medicine**

- Represents the amount of active ingredient in each dosage unit (/tab, /cap, /5ml)
- For external preparations (%age of active ingredient)

- **Units**

- As whole number of units
 - 100mg rather than 0.1g OR 6 μ g instead of 0.006mg

- **Batch identification**

- **Diluted products**

- Have reduced shelf life
- Indicate the degree of dilution

- FOR >1 Ing.

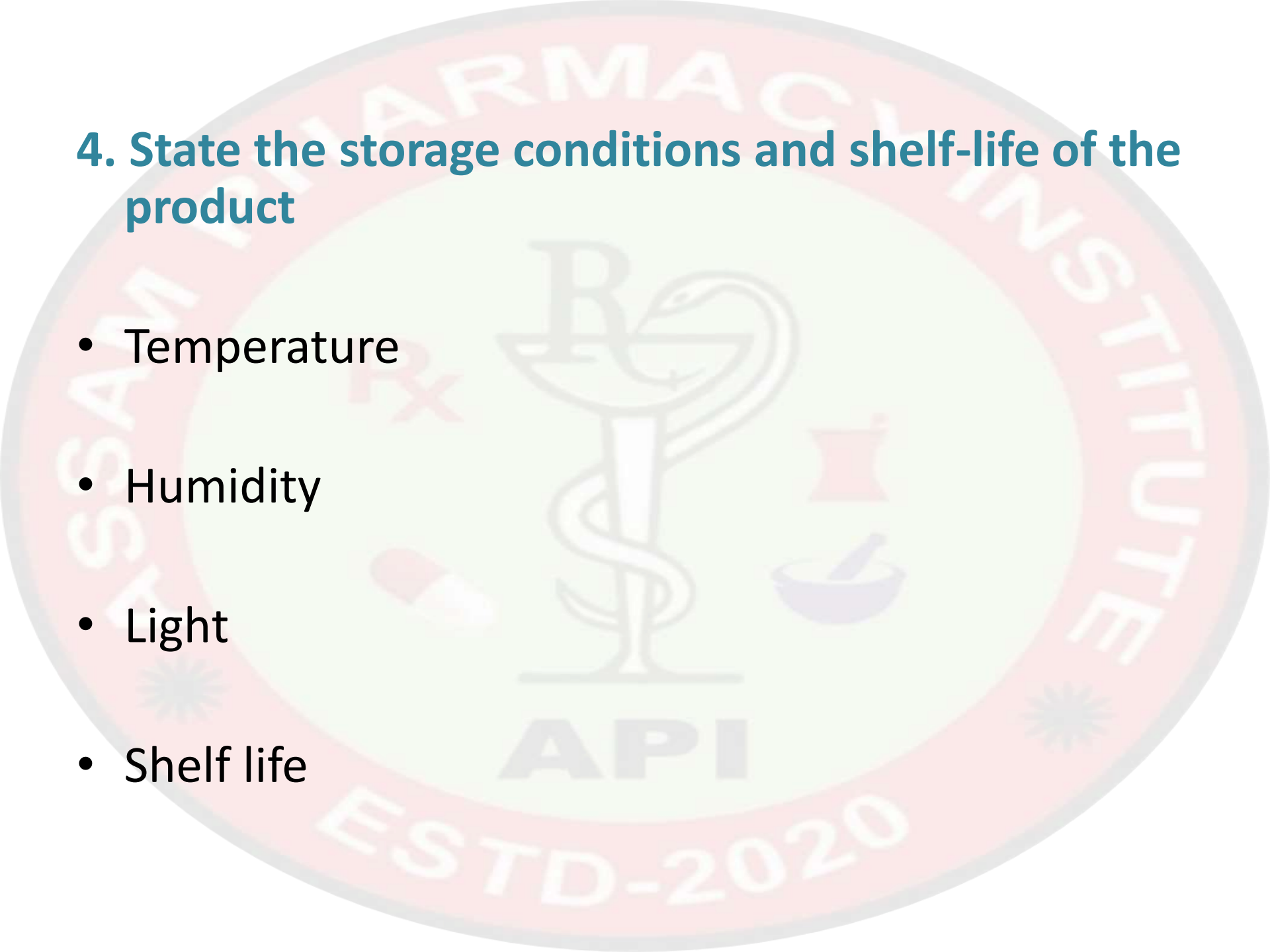
**Diluted Chloral Mixture
Half Strength**

- FOR 1 Ing.

**Diluted Chloral Mixture BP
containing 250mg/5ml Chloral
Hydrate**

4. State the storage conditions and shelf-life of the product

- Temperature
- Humidity
- Light
- Shelf life



5. Give the patient clear and complete instructions on how to take or use the product

- Directions
 - Amount of drug to be taken
 - Frequency and timing of administration
 - Route of administration
 - Method of use
- Ambiguous information should be avoided
 - Three tablets to be taken daily (makes confusion)

CAUTIONARY AND ADVISORY LABELS



Cautionary and Advisory labels

- **FOR EXTERNAL USE ONLY**
(ointments, creams, dusting powders, gels etc.)
- **NOT TO BE TAKEN**
(for nasal, rectal, vaginal use)
Not to be swallowed in large amounts
(for mouth washes, gargles)
- **KEEP OUT OF REACH OF CHILDREN**
- **FOR ANIMAL TREATMENT ONLY**



Recommended Cautionary and Advisory labels

- **Drowsiness Warnings**

- Drowsiness, dizziness, blurred vision or difficulty in concentrating
 - For children's medicines

Warning. May cause drowsiness



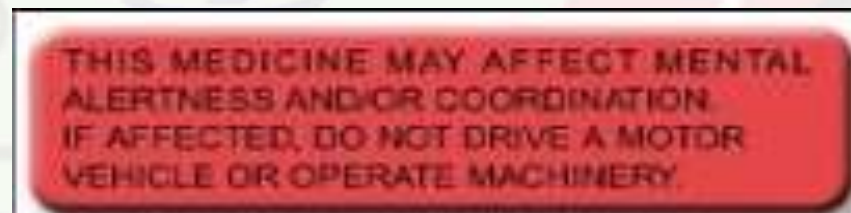
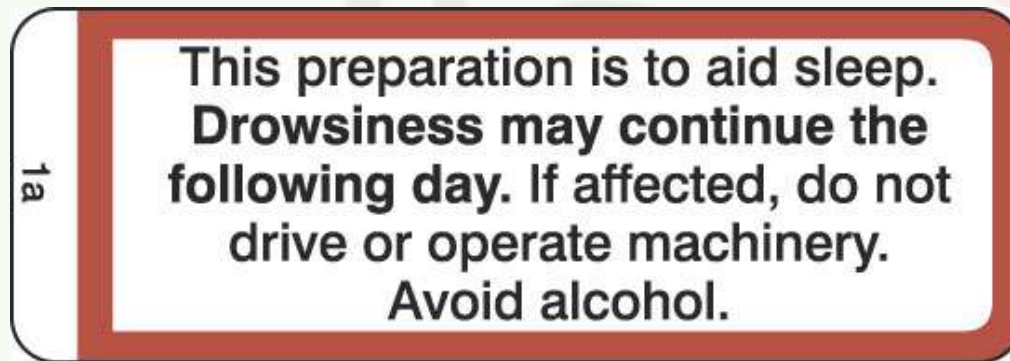
- Some medicines make patient more drowsy esp. when consuming alcohol



This medicine may cause drowsiness and may increase the effects of alcohol.

If affected, do not drive a motor vehicle or operate machinery.

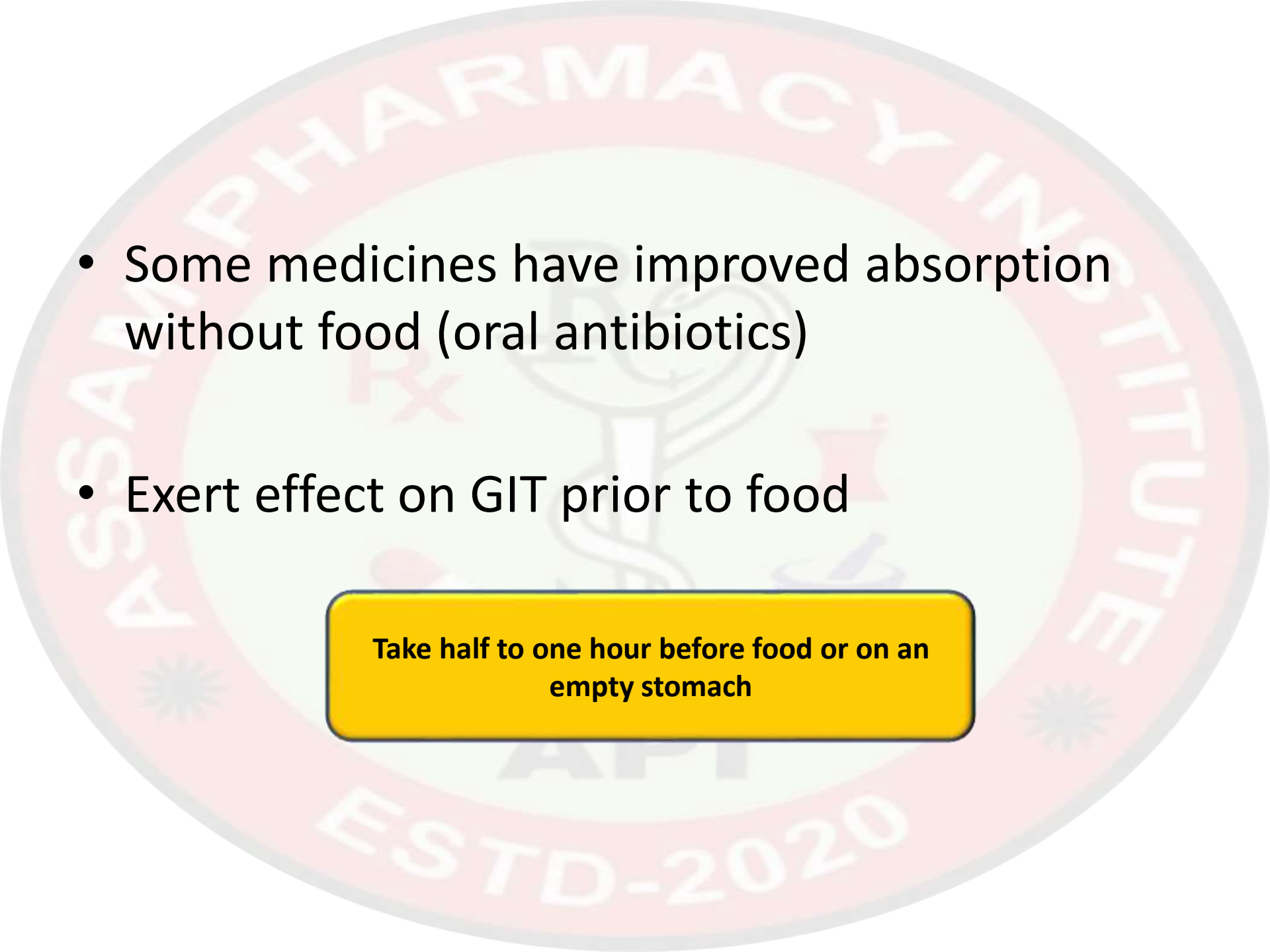
- Hypnotics used as sleep aids taken at bedtime may cause drowsiness persisting next day



- **Potential interactions with food or drink**
 - Products liable to cause GIT irritation
 - Better absorption with food

... with or after food



- 
- The background of the slide features a large, faint, circular logo for the Assam Pharmacy Institute. The logo is light pink and contains a central emblem with a caduceus (a staff with two snakes and wings) and a mortar and pestle. The text "ASSAM PHARMACY INSTITUTE" is written in a circular path around the emblem, and "ESTD-2020" is at the bottom. There are also small star-like symbols on the sides.
- Some medicines have improved absorption without food (oral antibiotics)
 - Exert effect on GIT prior to food

Take half to one hour before food or on an empty stomach

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute logo. The logo is circular with a red border. Inside the border, the text "ASSAM PHARMACY INSTITUTE" is written in a semi-circle at the top, and "ESTD-2020" is at the bottom. In the center of the logo is a stylized emblem featuring a caduceus (a staff with two snakes and wings) and a book.

- **Potential interactions with other medicines**

Do not take iron, milk or indigestion remedies at the same time of the day as this medicine

- The problem can be avoided by giving incompatible preparations 2hrs apart

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute logo. The logo is circular with a red border. Inside the border, the text "ASSAM PHARMACY INSTITUTE" is written in a semi-circle at the top, and "ESTD-2020" is at the bottom. In the center of the logo is a green circle containing a white caduceus (a staff with two snakes and wings) and a mortar and pestle. There are also small star-like symbols on the sides.

- **Special dosage instructions**

**Do not stop taking this medicine
except on your doctor's advice**

**Take at regular intervals. Complete
the prescribed course unless
otherwise directed**

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute logo. The logo is circular with a red border containing the text 'ASSAM PHARMACY INSTITUTE' in white. Inside the circle, there is a central emblem with a lamp and a mortar and pestle, and the text 'API' and 'ESTD-2012' are visible at the bottom.

- **Special Methods of Administration**

Dissolve or mix with water before taking.

. . . with plenty of water

. . . Swallow whole, not chewed

Dissolve under the tongue

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute logo. The logo is circular with a pink outer ring containing the text 'ASSAM PHARMACY INSTITUTE' at the top and 'ESTD-2020' at the bottom. Inside the ring is a light green circle containing a stylized 'B' with a snake coiled around it, and the letters 'API' below. Two small star-like symbols are also present on the left and right sides of the green circle.

- **Cautions in use**

Avoid exposure of skin to direct sunlight

This preparation may color the urine or stools

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute (API) logo. The logo is circular with a red border. Inside the border, the text "ASSAM PHARMACY INSTITUTE" is written in white, uppercase letters along the top arc, and "ESTD-2020" is written along the bottom arc. In the center of the logo is a caduceus (a staff with two snakes entwined and wings at the top). Below the caduceus, the letters "API" are written in a bold, sans-serif font. To the left of the caduceus is a small red and white capsule, and to the right is a small purple mortar and pestle.

Special Instructions For Particular Types Of Products

The background of the slide features a large, faint watermark of the Assam Pharmacy Institute (API) logo. The logo is circular with a pink outer ring containing the text 'ASSAM PHARMACY INSTITUTE' at the top and 'ESTD-2020' at the bottom. Inside the ring is a light green circle with a grey emblem in the center. The emblem depicts a caduceus (a staff with two snakes entwined and wings at the top) superimposed on a stylized map of Assam. Below the emblem, the letters 'API' are written in a bold, sans-serif font.

- Pressurized inhalations

Pressurized container, keep away from heat source including the sun. Do not puncture or burn even when empty.

Shake before using

- Applications

For external use only

- Capsules

**Swallow whole with a draught of
water**

- Creams

For external use only

Store in cool place but do not freeze

- Dusting powders

For external use only

**Not to be applied to open wounds or
weeping surfaces**

- Emulsions

Shake the bottle

- Enemas

For rectal use only

Shake before use

- Eye drops

Avoid contamination in use

Discard 28 days after first opening

- Gargles & Mouthwashes

Not to be swallowed in large amounts

- Gels

For external use

- Linctuses

**To be sipped and swallowed slowly
without the addition of water**

- Ointments, Pastes and Paints

For external use only

- Tablets

Dissolve or disperse in water before taking

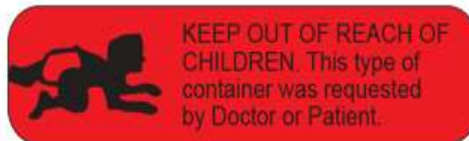
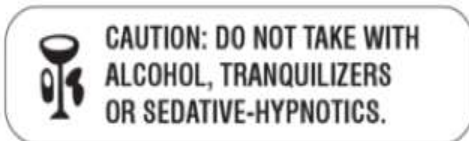
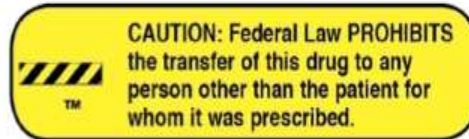
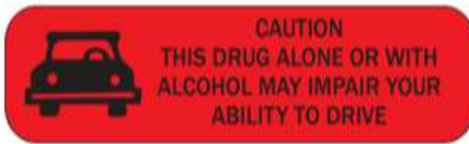
- For chewable tablets

Chew before swallowing

- For sustained-release/enteric coated tabs.

Do not chew or crush

AUXILLARY LABELS



Understanding Pictograms





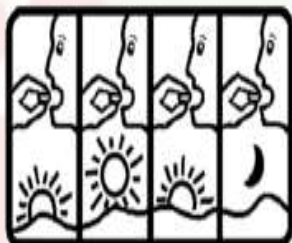
Take 1 hour before meals



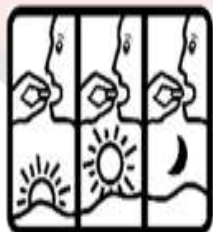
Take 1 hour after meals



Take 2 times a day



Take 4 times a day



Take 3 times a day



Do not store near heat or in sunlight



Take with meals



Wash hands/place drops in ear/wash hands again



Wash hands/place drops in nose/wash hands again



Wash hands/insert into vagina/wash hands again



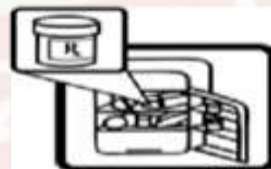
Do not store medicine where children can get in



Do not drink alcohol while taking this medicine



This medicine may make you drowsy



Store in refrigerator