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Guidelines for drug labeling design of medications for pediatric use

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Preface

Based on " The National Standards of the People's Republic of China" (GB/T 1.1-2020), "Drug Administration Law of the People's Republic of China", "Administrative Regulations on Package Inserts and Drug Labels" (State Food and Drug Administration Order No. 24, issued in 2006), this guideline was formulated with reference to "Guidelines for the labeling design of injections"(T/CNPPA3004-2019) while considering the characteristics of medications for pediatric use.

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Introduction

Children are not reduced version adults. They have significantly different drug absorption, distribution, metabolism and excretion process comparing to adults, and different age groups have unique physiological characteristics. Medications are subject to age restrictions or dose requirements when being used in pediatric population. Drug labels for children and adults should be clearly distinguishable, or there should be clear reminders of important contents involving pediatric use, to prevent harm caused by children's misuse. Therefore, in addition to fulfilling the basic requirements of drug label design, labels for pediatric use should also highlight the characteristics of pediatric medications, and important safety information should be clearly marked.

This guideline aims to instruct drug marketing authorization holders how to use key elements such as fonts, patterns, colors, layouts properly in drug label design to increase the identifiability of important contents, reduce clinical medication errors and ensure drug safety in pediatric population.

This guideline was formulated with reference to "the drug administration law of the people's Republic of China", "the provisions on the administration of drug instructions and labels"(Order No. 24 of the State Food and drug administration, issued in 2006, T/CNPPA3004-2019.

Drug marketing authorization holders, clinical institutions, label designers and manufacturers can refer to this guideline under the premise of following relevant national regulations.

All the pictures used in the guide are schematic diagrams. The drug names are for illustration purposes only. They are irrelevant to the actual drug properties.

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Guidelines for drug labeling design of medications for pediatric use

1.Scope

The guideline specifies terms, definitions, and design principles for drug labels on medications for pediatric use.

This guideline is applicable for guiding the graphic design and making of inner and outer labels of pediatric medications, including labels that is directly made (or printed) on the surface of packaging, and is made (or pasted) on the surface of packaging.

2. Normative references

Pharmacopoeia of the people's Republic of China (2020 Edition) (Volume IV)

3. Terms and definitions

The following terms and definitions apply to this guideline.

3.1 Medications for pediatric use: refers to drugs for exclusive use of children in the target age group and drugs that can be used for children.

3.2 Labeling: the label printed or affixed on the drug package, which can be divided into inner labels and outer labels.

3.3 Inner label: the label that directly contacts the drug packaging container.

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3.4 Outer label: the label of other packages except the inner label, which is usually divided into the minimum packaging label for marketing and packaging label for transportation and storage. The outer label in this document refers to the minimum packaging label for marketing (sale).

Note: If the minimum packaging for marketing is the packaging that directly contacts drugs, it is also within this meaning.

3.5 Special label: according to “the Chinese Pharmacopoeia 2020 Edition Four” General Rules 0100, the labels and instructions of narcotic drugs, psychotropic drugs, medical toxic drugs, radiopharmaceuticals, topical drugs and over-the-counter drugs must be printed with the prescribed identifications, usually known as specified labels, see Appendix A.

Note: The specified logo pattern should be marked in a fixed position on the upper right corner of the label, including the identifications that can be used for drugs passing the consistency evaluation, as shown in Appendix B.

3.6 High-alert medication: drugs that can cause serious injuries or deaths for patients if used improperly or medication errors occur. Although the occurance of medication errors in these drugs is not necessarily greater than that of others, the consequences are extremely serious, refer to Appendix C, for relevant varieties, see Appendix E.

3.7 Traceability code: a unique code assigned by the drug manufacturer on the minimum packaging of drugs. It can be a one-dimensional code or a two-dimensional code, or it can be marked with radio frequency identification (RFID) technology.

Note: By reading the drug traceability code, one can obtain information such as the manufacturer, drug specifications, approval number, batch number, and expiration date, and it’s mainly used for drug information (including instructions) query, drug circulation, traceability and anti-counterfeiting.

4. Design principles of drug labels on medications for pediatric use

4.1 Overview

Optimizing pediatric drug label design can improve the identifiability of important contents related to pediatric use, reduce errors during the process of drug filling, dispensing and administration, and prompt guardians to use special devices properly (if applicable), and prevent or reduce harm to children effectively.

The drug marketing authorization holder should establish regulations for the label design scheme review and approval system according to relevant national rules. In the process of developing and designing drug labels and packaging, the end users and their use environment should be considered, following the principles listed below.

4.2 Matching drug label information with package inserts

The designer, reviewer and manufacturer of the drug label are responsible for ensuring that the label content is consistent with the package insert.

4.3 Choose colors and patterns carefully

The color and figures on packaging/label of drugs for pediatric use should be clearly distinguished from other products (food, toys, etc.) to avoid misleading. Do not use pictures that may misguide children and cause them to take drugs by mistake. However, the psychological characteristics of children should also be considered, and appropriate colors and design elements should be adopted to alleviate children's fear and resistance to drugs.

4.4 Special identification on medications for pediatric use

It is recommended to use specific identifications to indicate pediatric use on the label (as shown in Figure 1 and Appendix D) to distinguish drugs for children clearly. It is recommended to place it in the upper right corner of the display surface.

Figure 1 The specific identification to indicate pediatric use

4.5 Indicate how to open the drug

Manufactured pediatric drugs using child-resistant packaging should be marked on the label, and the opening method should also be indicated if possible.

4.6 Mark the division/measuring method

In most cases, the dosing of pediatric drugs should base on weight or age, and the usual drug specifications cannot meet the clinical need. When being used in pediatric population, oral tablets require segmentation, and liquid formulation needs to be measured. In these scenarios, improper use of segmentation or measuring devices will cause dosing errors and bring risks to children's health. The package inserts of some varieties will specifically explain the method of dividing doses, and this should be clearly illustrated in the label design of pediatric medications.

4.6.1 Scored tablets

In the process of tablet compressing, drug manufacturers use molds to make tablet scores, and it can be split along the scored line according to the dosage requirements for use, in order to ensure the accurate dosage of the divided unit. The scored line should be reminded graphically on the drug label, as shown in Figure 2.

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Figure 2 Scored line icon, taking aspirin tablets as an example

4.6.2 Liquid formulations

When liquid preparations are used in pediatric patients, an accompanying measuring device is usually provided. It is necessary to use the measuring device to accurately measure the administered dose according to the package inserts. There should be an icon on the label to remind the guardian to use the dosing device when taking the product, as shown in Figure 3.

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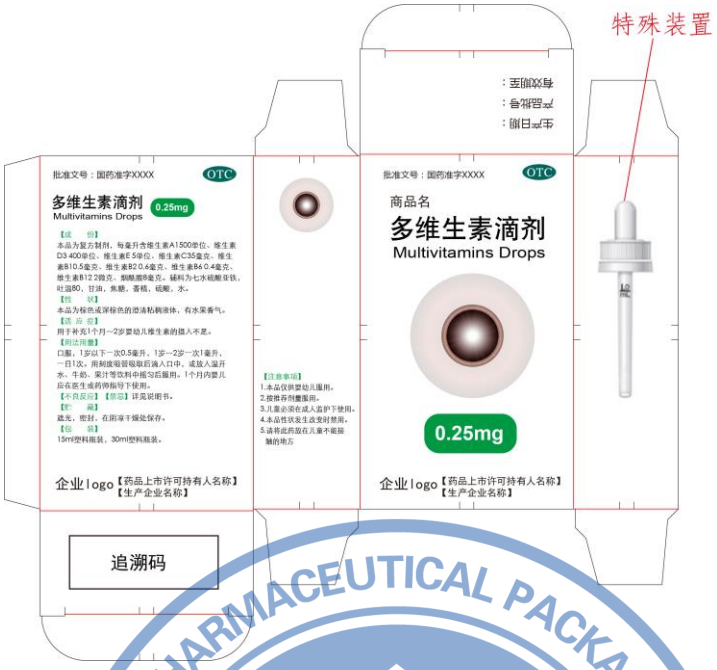

Figure 3 Liquid preparation measuring device, taking multivitamin drops as an example

4.7 Special dosage forms or drug delivery devices

For medications that require using special drug delivery devices (such as facial masks and nebulizers) for administration, if their packaging were the same or similar to other dosage forms (such as injections), the correct route and method of administration should be indicated on each key face of the label to prevent misuse. As shown in Figure 4.

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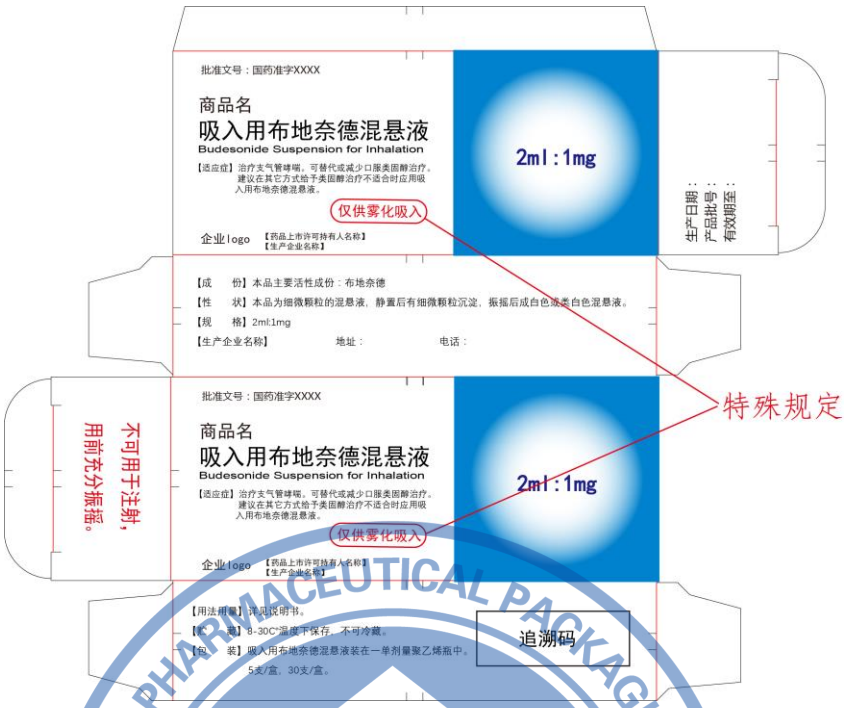

Figure 4 Warnings on the route of administration, taking budesonide suspension for inhalation as an example

4.8 Mark the applicable age group

If a drug is applicable to a specific pediatric age group, it should be indicated on the drug label clearly, as shown in Figure 5, Figure 6.

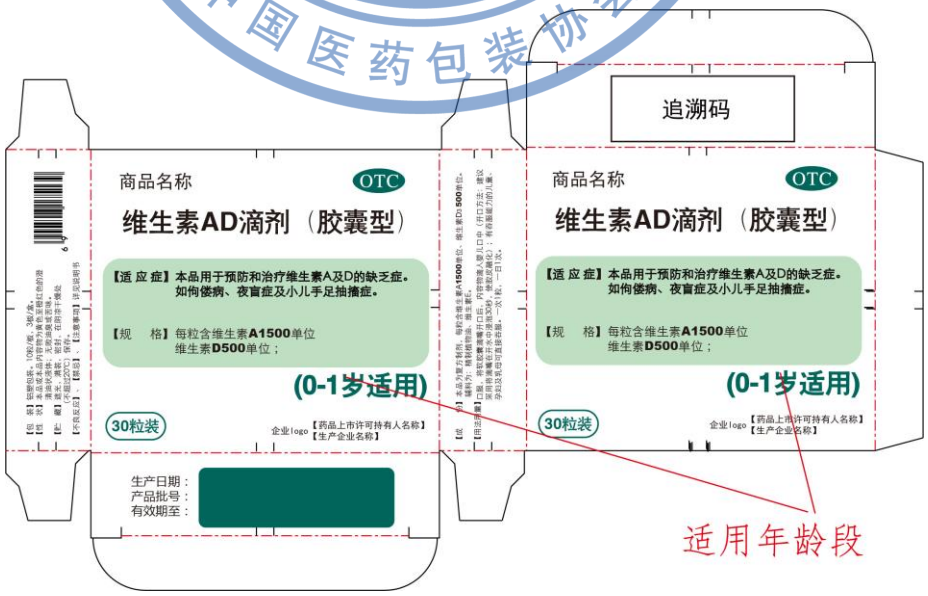

Figure 3 Identifications to indicate age restriction, taking vitamin AD drops (for 0-1 year old children) as an example

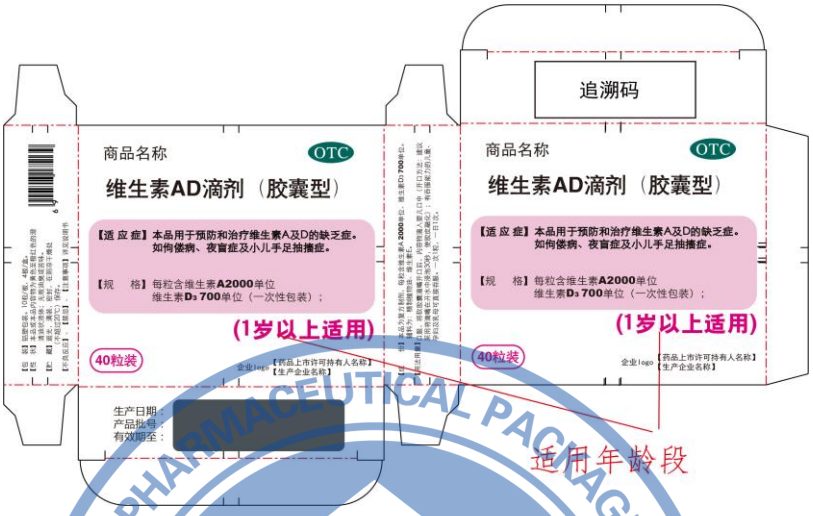

Figure 9 Identifications to indicate age restriction, taking vitamin AD drops (for children over 1 year old) as an example

4.9 Mark non-swallowable tablets with warning information

For dosage forms that are in shape of tablets but cannot be swallowed directly (such as effervescent tablets, tablets for external use), relevant warnings including “Do not take orally” should be clearly marked on the label to remind the guardian, and the correct instructions should be listed, as shown in Figure 7.

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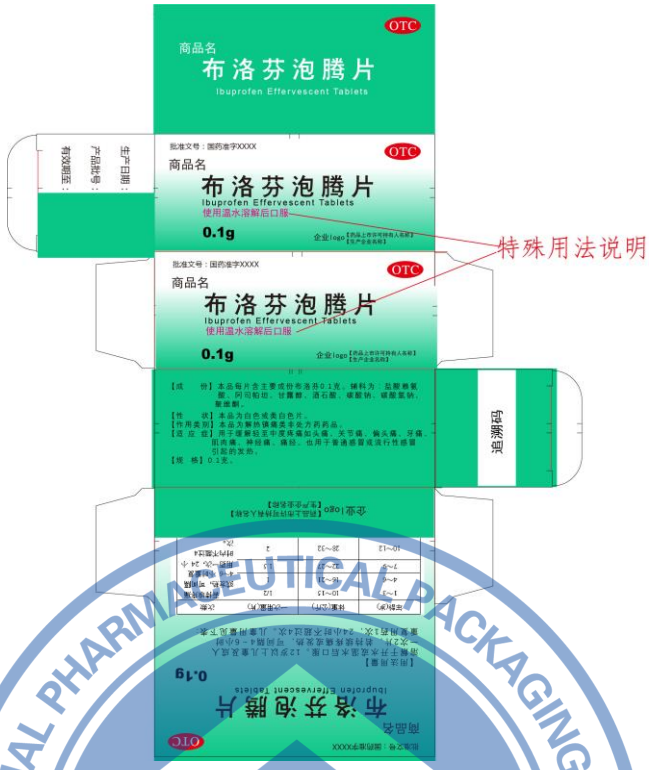

Figure 10 Warnings to prevent direct swallowing of the tablets, taking ibuprofen effervescent tablets as an example

4.10 Beyond use date of compounded solutions or suspensions

Some special dosage forms need to be prepared by specific methods before use, and there are time limits for the storage of compounded solutions. A suitable place should be reserved to mark the expiration date of the preparation solution to prevent using expired medications, as shown in Figure 8.

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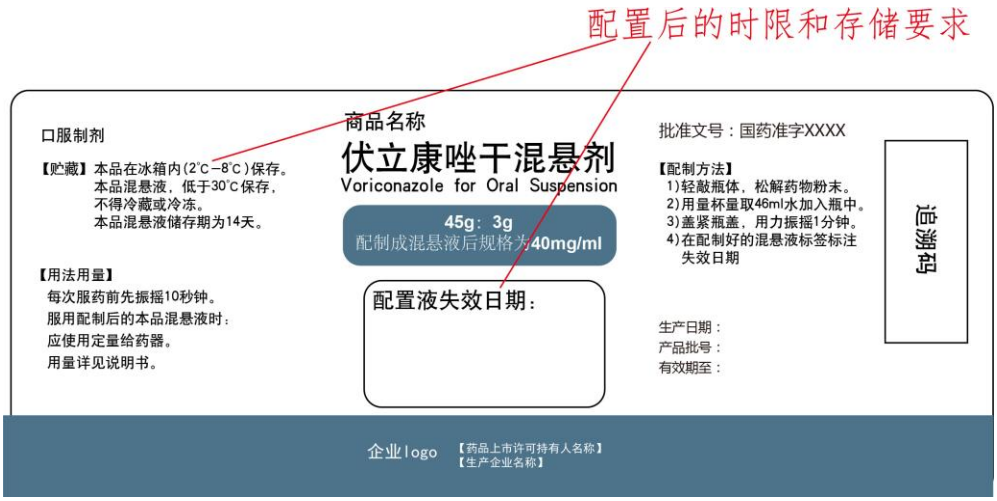

Figure 11 Time limit and expiration date of preparation solution, taking voriconazole for oral suspension as an example

4.11 The specifications of pediatric medications with the same generic name

For drugs having the same generic name, specifications commonly used in children should be clearly marked on the label, as shown in Figure 9.

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Figure 9 Special specifications of drugs for pediatric use, taking glucose and sodium chloride injection as an example

4.12 High-alert pediatric medications with the same generic name but different specifications

Drugs with the same generic name but different specifications are likely to have overdose issues or being used insufficiently during drug administration, especially for those with a narrow therapeutic window. "Pediatric use" and drug specifications should be clearly indicated on the label to prevent the potential risk for pediatric population. High-alert drugs should be marked with specified identification, as shown in Figure 10.

Figure 10 A illustration of a high-alert drug for pediatrics with the same generic name, taking digoxin injection (0.1mg/ml) as an example

4.13 Labeling of medications for disposable use (single dose)

Drug varieties that are only for disposable use as stipulated in the package inserts should be clearly marked on the label, as shown in Figure 11.

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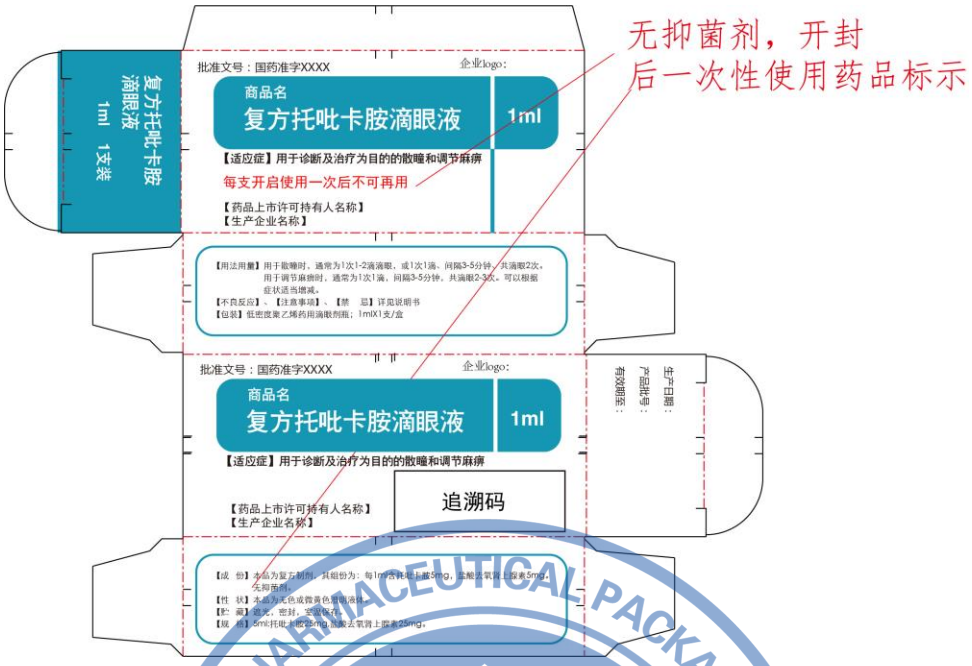

Figure 11 Warnings of drugs for disposable use only after opening, taking compound tropicamide eye drops (without bacteriostatic agent) as an example

4.14 Information that needs special attention

Important information contained in the package inserts that needs special attention, should be marked on the label, including black box warnings, contraindications in pediatric population, special using methods, etc..

When drug excipients may bring potential risks to children's health, the content indicated in the package inserts should be clearly marked on the label. For example, aminophylline injection (2ml: 0.25g) contains benzyl alcohol, and its intramuscular injection is prohibited in children. As shown in Figure 12.

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Figure 12 A illustration of drug label if containing potential risky excipients, taking aminophylline injection as an example

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