

A woman with long, dark, straight hair is seen from the back, looking towards a pharmacy counter. The shelves behind her are filled with various boxes of medicine. The background is slightly blurred, focusing attention on the text overlays.

Consumer Behavior Research:

Evaluating When Product Characteristics
Might Introduce Problems for Consumers

**Nonprescription Analgesic/Antipyretic
Drug Development in Children 2 to
Less Than 12 Years of Age**

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Why me?

- Pediatrician
- Hospital-based pediatrics
- Senior Vice President at PEGUS Research, Inc.
 - CRO specializing in Consumer Behavior Research
 - Primarily nonprescription medications/Rx to OTC switch



Disclosures

- I work for PEGUS Research, Inc.
- PEGUS Research is contracted by sponsor companies
 - Consulting
 - Conducting consumer behavior research
- In that role, I interface with teams at many consumer healthcare and pharma companies
- I have no direct relationship (financial or otherwise) with sponsor companies

**COMING
SOON**



DUPLINOL

PAIN RELIEVER



Introducing Duplinol!



DUPLINOL
PAIN RELIEVER

- Oral suspension pain reliever
- Fixed combination product with 2 active ingredients
 - Acetaminophen
 - Formulated to be longer acting
 - Novelprofen
 - New NSAID with longer half-life
 - More effective for pain than existing OTC NSAIDS
 - Should not be used with other NSAIDS
 - Contraindicated for use longer than 5 days
 - Contraindicated in children with infections
 - Dosed every 8 hours
- Supplied with a new “dial-a-dose” dosing device

Potential Consumer Behavior Issues Introduced by Duplinol Characteristics

Product Characteristic	Potential Issue
Combination product with two active ingredients	Do consumers recognize that there are multiple active ingredients?
<ul style="list-style-type: none">• Contains acetaminophen	If given with other acetaminophen-containing products could result in inadvertent overdose.
<ul style="list-style-type: none">• Contains novelprofen	If given with other NSAID-containing products could result in increased risk of adverse events.
<ul style="list-style-type: none">• Should not be used in children with infections	This differs from other common pediatric pain medications, which are also used for fever. Could this difference lead to inadvertent misuse?
<ul style="list-style-type: none">• Should not be used for more than 5 days	If given for longer than recommended could lead to increased risk of adverse events.

Potential Consumer Behavior Issues Introduced by Duplinol Characteristics

Product Characteristic	Potential Issue
Every 8-hour dosing	This dosing schedule differs from other common nonprescription pediatric pain and fever medicines, and if not understood could lead to underdosing (and reduction in effectiveness) or overdosing (with an increase in risk).
“Dial-a-dose” oral dosing device	Can consumers use this device to deliver an accurate dose? Failure to use appropriately could lead to underdosing (and reduction in effectiveness) or overdosing (with an increase in risk).



25%
Licht für Ihre Augen
Medfil plus Forte
3,54 mg

+ PHARMACY

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Consumer Behavior Research: Common Study Types

Study Type	Description
Label Comprehension: LC	Do consumers understand the key communication messages from the Drug Facts label (and other labeling elements)? Participants from the general population are shown product labeling and then asked scenario-based questions aimed at demonstrating whether they understand label messages.
Label Discernment: LD	Do consumers understand what makes this product different from others? Participants from the general population are shown product labeling and asked questions to assess understanding of important distinguishing characteristics.
Self-Selection: SS	Can consumers decide whether a product is appropriate for them to use, without the guidance of a learned intermediary (healthcare professional)? Participants from the target user population (with and without contraindications to use) are shown product labeling and asked whether the product is okay or not okay for them to use.

Consumer Behavior Research: Common Study Types

Study Type	Description
Human Factors: HF	Can consumers use the devices or systems associated with a product in a manner consistent with the instructions for use, and which is likely to lead to safe and effective use? Use-related risk is defined. Participants are shown product labeling and are asked to demonstrate use of the device or system in question. Such use is evaluated with an eye toward rating how critical tasks are performed and identifying potential pitfalls.
Actual Use: AU	Can consumers actually use the product without guidance from a healthcare professional in a manner consistent with the labeling? Participants interested in using the product are recruited and given access to the product in a simulated nonprescription environment. Use behaviors of interest are measured.

Potential Issues Introduced by Duplinol Characteristics

Product Characteristic	Potential Issue	Studies
Combination product with two active ingredients	Do consumers recognize that there are multiple active ingredients?	LC, LD
<ul style="list-style-type: none">Contains acetaminophen	If given with other acetaminophen-containing products could result in inadvertent overdose.	LC, LD, ?AU
<ul style="list-style-type: none">Contains novelprofen	If given with other NSAID-containing products could result in increased risk of adverse events.	LC, LD, ?AU
<ul style="list-style-type: none">Should not be used in children with infections	This differs from other common pediatric pain medications, which are also used for fever. Could this difference lead to inadvertent misuse?	LC, SS, ?AU
<ul style="list-style-type: none">Should not be used for more than 5 consecutive days	If given for longer than recommended could lead to increased risk of adverse events.	LC, AU

Potential Issues Introduced by Duplinol Characteristics

Product Characteristic	Potential Issue	Studies
Every 8-hour dosing	This dosing schedule differs from other common nonprescription pediatric pain and fever medicines, and if not understood could lead to underdosing (and reduction in effectiveness) or overdosing (with an increase in risk).	LC, AU
“Dial-a-dose” oral dosing device	Can consumers use this device to deliver an accurate dose? Failure to use appropriately could lead to underdosing (and reduction in effectiveness) or overdosing (with an increase in risk).	HF

**Many
Thanks!**

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